

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 141 and 142

[EPA-HQ-OW-2008-0878; FRL-9684-8]

RIN 2040-AD94

National Primary Drinking Water Regulations: Revisions to the Total Coliform Rule

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final Rule.

SUMMARY: The Environmental Protection Agency (EPA or the Agency) is finalizing revisions to the 1989 Total Coliform Rule (TCR). The Revised Total Coliform Rule (RTCR) offers a meaningful opportunity for greater public health protection beyond the 1989 TCR. Under the RTCR there is no longer a monthly maximum contaminant level (MCL) violation for multiple total coliform detections. Instead, the revisions require systems that have an indication of coliform contamination in the distribution system to assess the problem and take corrective action that may reduce cases of illnesses and deaths due to potential fecal contamination and waterborne pathogen exposure. This final rule also updates provisions in other rules that reference analytical methods and other requirements in the 1989 TCR (e.g., Public Notification and Ground Water Rules). These revisions are in accordance with the 1996 Safe Drinking Water Act (SDWA) Amendments, which require EPA to review and revise, as appropriate, each national primary drinking water regulation no less often than every six years. These revisions also conform with the SDWA provision that requires any revision to “maintain, or provide for greater, protection of the health of persons.” As with the 1989 TCR, the RTCR applies to all public water systems.

DATES: This final rule is effective on **[INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]**. For judicial purposes, this final rule is promulgated as of **[INSERT DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]**. The compliance date for the rule requirements is April 1, 2016. The incorporation by reference of certain publications listed in the rule is approved by the Director of the *Federal Register* (FR) as of **[INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]**.

ADDRESSES: EPA has established a docket for this action under Docket ID No. EPA-HQ-OW-2008-0878. All documents in the docket are listed on the <http://www.regulations.gov> website. Although listed in the index, some information is not publicly available, e.g., Confidential Business Information or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available either electronically through <http://www.regulations.gov> or in hard copy at the Water Docket, EPA/DC, EPA West, Room 3334, 1301 Constitution Ave., NW, Washington, DC. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566-1744, and the telephone number for the Water Docket is (202) 566-2426.

FOR FURTHER INFORMATION CONTACT: Sean Conley, Standards and Risk Management Division, Office of Ground Water and Drinking Water (MC-4607M), Environmental Protection Agency, 1200 Pennsylvania Ave., NW, Washington, DC 20460; telephone number: (202) 564-1781; e-mail address: conley.sean@epa.gov. For general information, contact the Safe Drinking Water Hotline, telephone number: (800) 426-4791. The

Safe Drinking Water Hotline is open Monday through Friday, excluding legal holidays, from 10 a.m. to 4 p.m. Eastern time.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Regulated Categories and Entities

Entities potentially regulated by the RTCR are all public water systems (PWSs). Regulated categories and entities include the following:

Category	Examples of regulated entities
Industry	Privately-owned community water systems (CWSs), transient non-community water systems (TNCWSs), and non-transient non-community water systems (NTNCWSs).
Federal, State, Tribal, and local governments	Publicly-owned CWSs, TNCWSs, and NTNCWSs.

This table is not intended to be exhaustive, but rather provides a guide for readers regarding entities regulated by this action. This table lists the types of entities that EPA is now aware could potentially be regulated by this action. Other types of entities not listed in the table could also be regulated. To determine whether your facility is regulated by this action, you should carefully examine the definition of “public water system” in § 141.2 and the section entitled “Coverage” in § 141.3 in title 40 of the Code of Federal Regulations (CFR), and the applicability criteria in § 141.851(b) of this rule. If you have questions regarding the applicability of this action to a particular entity, consult the person listed in the preceding **“FOR FURTHER INFORMATION CONTACT”** section.

B. Copies of This Document and Other Related Information

This document is available for download at **[INSERT WEBSITE ADDRESS]**. For other related information, see preceding discussion on docket. EPA also prepared a *Response to Comments Document* that addresses the comments received during the comment period (to access this document, search for Docket ID No. EPA-HQ-OW-2008-0878 in www.regulations.gov).

C. Executive Summary

EPA is finalizing the Revised Total Coliform Rule (RTCR). The RTCR maintains the purpose of the 1989 Total Coliform Rule (TCR) to protect public health by ensuring the integrity of the drinking water distribution system and monitoring for the presence of microbial contamination. EPA anticipates greater public health protection under the RTCR, as it requires public water systems (PWSs) that are vulnerable to microbial contamination to identify and fix problems, and it establishes criteria for systems to qualify for and stay on reduced monitoring, thereby providing incentives for improved water system operation.

The RTCR, as with the 1989 TCR, is the only microbial drinking water regulation that applies to all PWSs. Systems are required to meet a legal limit (i.e., maximum contaminant level (MCL)) for *E. coli*, as demonstrated by required monitoring. The RTCR specifies the frequency and timing of the microbial testing by water systems based on population served, system type, and source water type. The rule also requires public notification when there is a potential health threat as indicated by monitoring results, and when the system fails to identify and fix problems as required.

The entities potentially affected by the RTCR are PWSs that are classified as community water systems (CWSs) (e.g., systems that provide water to year-round residents in places like homes or apartment buildings) or non-community water systems (NCWSs) (e.g., systems that

provide water to people in locations such as schools, office buildings, restaurants, etc.); State primacy agencies; and local and tribal governments. The RTCR applies to approximately 155,000 PWSs that serve approximately 310 million (M) individuals.

The RTCR establishes a health goal (maximum contaminant level goal, or MCLG) and an MCL for *E. coli*, a more specific indicator of fecal contamination and potential harmful pathogens than total coliforms. EPA replaces the MCLG and MCL for total coliforms with a treatment technique for coliforms that requires assessment and corrective action. Many of the organisms detected by total coliform methods are not of fecal origin and do not have any direct public health implication.

Under the treatment technique for coliforms, total coliforms serve as an indicator of a potential pathway of contamination into the distribution system. A PWS that exceeds a specified frequency of total coliform occurrence must conduct an assessment to determine if any sanitary defects exist (a sanitary defect is defined by the RTCR as a “defect that could provide a pathway of entry for microbial contamination into the distribution system or that is indicative of a failure or imminent failure of a barrier that is already in place”); if any are found, the system must correct them. In addition, under the treatment technique requirements, a PWS that incurs an *E. coli* MCL violation must conduct an assessment and correct any sanitary defects found.

The RTCR links monitoring frequency to compliance monitoring results and system performance. It provides criteria that well-operated small systems must meet to qualify for and stay on reduced monitoring. It requires increased monitoring for high-risk small systems with unacceptable compliance history. It also requires some new monitoring requirements for seasonal systems (such as state and national parks).

The RTCR eliminates public notification requirements based only on the presence of total coliforms. Total coliforms in the distribution system may indicate a potential pathway for contamination but by themselves do not indicate a health threat. Instead, the RTCR requires public notification when an *E. coli* MCL violation occurs, indicating a potential health threat, or when a PWS fails to conduct the required assessment and corrective action.

EPA believes that the provisions of the RTCR will improve public health protection by requiring assessment and corrective action and providing incentives for improved operation. The estimated net incremental cost of the RTCR is \$14 million annually at either a three or seven percent discount rate. This represents total increased costs relative to 1989 TCR provisions. PWSs are estimated to incur approximately 97 percent of the rule's net annualized present value costs at the three percent discount rate. States and other primacy agencies incur the remaining costs.

Abbreviations Used in This Document

AGI	Acute Gastrointestinal Illness
AIDS	Acquired Immune Deficiency Syndrome
AIP	Agreement in Principle
AWWA	American Water Works Association
ATP	Alternate Test Procedure
BAT	Best Available Technology
C	Celsius
CCR	Consumer Confidence Report
CDC	Centers for Disease Control and Prevention
CFR	<i>Code of Federal Regulations</i>
COI	Cost of Illness
CWS	Community Water System
DBP	Disinfection Byproduct
DWC	Drinking Water Committee
EA	Economic Analysis
EC-MUG	EC Medium with MUG
EPA	United States Environmental Protection Agency
ERS	Economic Research Service
ETV	Environmental Technology Verification
FR	<i>Federal Register</i>

GWR	Ground Water Rule
GWUDI	Ground Water Under the Direct Influence of Surface Water
HRRCA	Health Risk Reduction and Cost Analysis
HUS	Hemolytic Uremic Syndrome
ICR	Information Collection Request
IESWTR	Interim Enhanced Surface Water Treatment Rule
M	Million
MCL	Maximum Contaminant Level
MCLG	Maximum Contaminant Level Goal
mg/L	Milligrams per Liter
ml	Milliliters
MRDL	Maximum Residual Disinfectant Level
MUG	4-methylumbelliferyl-Beta-D-glucuronide
NCWS	Non-community Water System
NDWAC	National Drinking Water Advisory Council
NPDWR	National Primary Drinking Water Regulation
NTNCWS	Non-Transient Non-Community Water System
NTU	Nephelometric Turbidity Unit
OMB	Office of Management and Budget
O&M	Operation and Maintenance
PN	Public Notification
PWS	Public Water System
RFA	Regulatory Flexibility Act
RTCR	Revised Total Coliform Rule
SAB	Science Advisory Board
SBA	Small Business Administration
SDWA	Safe Drinking Water Act
SDWIS	Safe Drinking Water Information System
SDWIS/FED	Safe Drinking Water Information System Federal Version
SOP	Standard Operating Procedure
Stage 1 DBPR	Stage 1 Disinfectants and Disinfection Byproducts Rule
Stage 2 DBPR	Stage 2 Disinfectants and Disinfection Byproducts Rule
SWTR	Surface Water Treatment Rule
TCR	Total Coliform Rule
TCRDSAC	Total Coliform Rule / Distribution System Advisory Committee
TMF	Technical, Managerial, and Financial
TNCWS	Transient Non-Community Water System
TWG	Technical Work Group
T&C	Technology and Cost
US	United States
UV	Ultraviolet

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II. Background

A. Statutory Authority

The Safe Drinking Water Act (SDWA) requires the EPA to review and revise, as appropriate, each existing national primary drinking water regulation (NPDWR) no less often than every six years (SDWA section 1412(b)(9), 42 U.S.C. 300g-1(b)(9)). In 2003, EPA completed its review of the 1989 TCR (USEPA 1989a, 54 FR 27544, June 29, 1989) and 68 NPDWRs for chemicals

that were promulgated prior to 1997 (USEPA 2003, 68 FR 42908, July 18, 2003). The purpose of the review was to identify new health risk assessments, changes in technology, and other factors that would provide a health-related or technological basis to support a regulatory revision that would maintain or improve public health protection. In the Six-Year Review 1 determination published in July 2003 (USEPA 2003, 68 FR 42908, July 18, 2003), EPA stated its intent to revise the 1989 TCR.

B. Purpose of the Rule

EPA promulgated the 1989 TCR to decrease the risk of waterborne illness. Among all SDWA rules promulgated for preventing waterborne illness, only the TCR applies to all PWSs, making the rule an essential component of the multi-barrier approach in public health protection against endemic and epidemic disease. In combination with the other SDWA rules (e.g., the Ground Water Rule (GWR) (USEPA 2006c, 71 FR 65574, November 8, 2006) and the suite of surface water treatment rules (USEPA 1989b; USEPA 1998b; USEPA 2002; USEPA 2006d)), the RTCR will better address the 1989 TCR objectives and enhance the multi-barrier approach to protecting public health, especially with respect to small ground water PWSs.

In recent years, the number of violations under the 1989 TCR have remained relatively steady, as shown and discussed in Exhibit 4.11 and Appendix G of the *Economic Analysis for the Final Revised Total Coliform Rule* (RTCR EA) (USEPA 2012a). EPA believes that this is reflective of a steady state among PWSs complying with the 1989 TCR and any improvements likely to occur under that rule have largely been achieved. In outlining recommendations for further reductions in occurrence, EPA and the Total Coliform Rule Distribution System Advisory Committee (TCRDSAC) developed an Agreement in Principle (AIP) (USEPA 2008c), which became the basis of the proposed and final RTCR. See section II.C.1 of this preamble,

Total Coliform Distribution System Advisory Committee (TCRDSAC), for more information about the TCRDSAC and the AIP.

The RTCR aims for greater public health protection than the 1989 TCR in a cost-effective manner by: (1) maintaining the objectives of the 1989 TCR (i.e., to evaluate the effectiveness of treatment, to determine the integrity of the distribution system, and to signal the possible presence of fecal contamination); (2) reducing the potential pathways of contamination into the distribution system (see section II.D of this preamble, *Public Health Concerns Addressed by the Revised Total Coliform Rule*); (3) using the optimal indicator for the intended objectives (i.e., using total coliforms as an indicator of system operation and condition rather than an immediate public health concern and using *E. coli* as a fecal indicator (see sections II.D, *Public Health Concerns Addressed by the Revised Total Coliform Rule*, and III.B, *Rule Construct: MCLG and MCL for E. coli and Coliform Treatment Technique*, of this preamble)); (4) requiring more stringent standards than those of the 1989 TCR for systems to qualify for reduced monitoring (see sections III.C.1.b.iii, *Reduced monitoring*, and III.C.1.c.iii, *Reduced monitoring*, of this preamble); and (5) requiring systems that may be vulnerable to contamination, as indicated by their monitoring results and by the nature of their operation (e.g., seasonal systems), to monitor more frequently and have in place procedures that will minimize the incidence of contamination (e.g., requiring start-up procedures for seasonal systems) (see sections III.C.1.b.iv, *Increased monitoring*, III.C.1.c.iv, *Requirements for returning to monthly monitoring*, and III.C.1.f, *Seasonal systems*, of this preamble). EPA, therefore, anticipates greater public health protection under the RTCR compared to the 1989 TCR because of the RTCR's more preventive approach to identifying and fixing problems that affect or may affect public health.

C. Rule Development

1. Total Coliform Rule Distribution System Advisory Committee (TCRDSAC)

The revisions to the 1989 TCR are primarily based on the recommendations of the Total Coliform Rule Distribution System Advisory Committee (“TCRDSAC” or the “advisory committee”). EPA established the TCRDSAC in June 2007 in accordance with the provisions of the Federal Advisory Committee Act, 5 U.S.C. App.2, 9(c), to provide recommendations to EPA on revisions to the 1989 TCR and on what information about distribution system issues is needed to better understand and address possible public health impacts from potential degradation of drinking water quality in distribution systems (USEPA 2007a, 72 FR 35869, June 29, 2007).

All advisory committee members agreed to a set of recommendations and signed a final Agreement in Principle (AIP) in September 2008. Pursuant to the AIP, EPA on July 14, 2010 proposed revisions to the 1989 TCR (USEPA 2010a, 75 FR 40926, July 14, 2010) that, to the maximum extent consistent with EPA’s legal obligations, had the same substance and effect as the elements of the AIP. The AIP and details about the advisory committee can be found at EPA’s website at

http://water.epa.gov/lawsregs/rulesregs/sdwa/tcr/regulation_revisions_tcrdsac.cfm.

2. Stakeholder involvement

In accordance with one of the recommendations of the TCRDSAC, EPA held two annual stakeholder meetings, prior to publishing the proposed revisions, to which all advisory committee members and the public at large were invited. In April 2009 and May 2010, EPA held these stakeholder meetings to provide updates and an opportunity for stakeholders to provide feedback on the development of a proposed RTCR that had the same substance and effect as the recommendations in the AIP.

EPA proposed the RTCR on July 14, 2010 (USEPA 2010a, 75 FR 40926, July 14, 2010) and requested public comment. EPA received approximately 150 comment letters on the proposal and considered the comments in making revisions to the final RTCR. Key issues raised by the commenters are discussed in their corresponding sections of this preamble. A *Response to Comments Document* is available in the docket of the RTCR (search for Docket ID No. EPA-HQ-OW-2008-0878 in *www.regulations.gov*).

During the public comment period for the proposed RTCR, EPA also held several meetings to solicit and provide the public with information about the provisions of the proposed rule. In addition to consulting with the advisory committee and holding stakeholder meetings, EPA consulted with specific stakeholders such as the National Drinking Water Advisory Council (NDWAC), the Science Advisory Board (SAB), and Tribal representatives, among others. These consultations are discussed in section VII of this preamble, *Statutory and Executive Order Review*.

D. Public Health Concerns Addressed by the Revised Total Coliform Rule

1. Public health concerns, fecal contamination, and waterborne pathogens

The RTCR aims to increase public health protection through the reduction of potential pathways of entry for fecal contamination into the distribution system. Since these potential pathways represent vulnerabilities in the distribution system whereby fecal contamination and/or waterborne pathogens, including bacteria, viruses and parasitic protozoa could possibly enter the system, the reduction of these pathways in general should lead to reduced exposure and associated risk from these contaminants. Fecal contamination and waterborne pathogens can cause a variety of illnesses, including acute gastrointestinal illness (AGI) with diarrhea, abdominal discomfort, nausea, vomiting, and other symptoms. Most AGI cases are of short

duration and result in mild illness. Other more severe illnesses caused by waterborne pathogens include hemolytic uremic syndrome (HUS) (kidney failure), hepatitis, and bloody diarrhea (WHO 2004). Chronic disease such as irritable bowel syndrome, renal impairment, hypertension, cardiovascular disease and reactive arthritis can result from infection by a waterborne agent (Clark *et al.* 2008; Clark *et al.* 2010; Moorin *et al.* 2010).

When humans are exposed to and infected by waterborne enteric pathogens, the pathogens become capable of reproducing in the gastrointestinal tract. As a result, healthy humans shed pathogens in their feces for a period ranging from days to weeks. This shedding of pathogens often occurs in the absence of any signs of clinical illness. Regardless of whether a pathogen causes clinical illness in the person who sheds it in his or her feces, the pathogen being shed may infect other people directly by person-to-person spread, contact with contaminated surfaces, and other means referred to as secondary spread. As a result, waterborne pathogens that are initially waterborne may subsequently infect other people through a variety of routes (WHO 2004). Sensitive subpopulations are at greater risk from waterborne disease than the general population (Gerba *et al.* 1996). For a discussion of sensitive subpopulations, see section VII.L of this preamble, *Impacts on Sensitive Subpopulations as Required by Section 1412(b)(3)(c)(i)(V) of the 1996 Amendments of the Safe Drinking Water Act (SDWA)*.

2. Indicators

Total coliforms are a group of closely related bacteria that, with a few exceptions, are not harmful to humans. Coliforms are abundant in the feces of warm-blooded animals, but can also be found in aquatic environments, in soil, and on vegetation. Coliform bacteria may be transported to surface water by run-off or to ground water by infiltration. Total coliforms are common in ambient water and may be injured by environmental stresses such as lack of

nutrients, and water treatments such as chlorine disinfection, in a manner similar to most bacterial pathogens and many viral enteric pathogens (including fecal pathogens). EPA considers total coliforms to be a useful indicator that a potential pathway exists through which fecal contamination can enter the distribution system. This is because the absence (versus the presence) of total coliforms in the distribution system indicates a reduced likelihood that fecal contamination and/or waterborne pathogens are occurring in the distribution system.

Under the 1989 TCR, each total coliform-positive sample is assayed for either fecal coliforms or *E. coli*. Fecal coliform bacteria are a subgroup of total coliforms that traditionally have been associated with fecal contamination. Since the promulgation of the 1989 TCR, more information and understanding of the suitability of fecal coliform and *E. coli* as indicators have become available. Study has shown that the fecal coliform assay is imprecise and too often captures bacteria that do not originate in the human or mammal gut (Edberg *et al.* 2000). On the other hand, *E. coli* is a more restricted group of coliform bacteria that almost always originate in the human or animal gut (Edberg *et al.* 2000). Thus, *E. coli* is a better indicator of fecal contamination than fecal coliforms. The provisions of the RTCR reflect the improved understanding of the value of total coliforms and *E. coli* as indicators.

3. Occurrence of fecal contamination and waterborne pathogens

a. Presence of fecal contamination. Fecal contamination is a very general term that includes all of the organisms found in feces, both pathogenic and nonpathogenic. Fecal contamination can occur in drinking water both through use and inadequate treatment of contaminated source water as well as direct intrusion of fecal contamination into the drinking water distribution system. Lieberman *et al.* (1994) discuss the general association between fecal contamination and waterborne pathogens. Biofilms in distribution systems may harbor

waterborne bacterial pathogens and accumulate enteric viruses and parasitic protozoa (Skraber *et al.* 2005; Helmi *et al.* 2008). Waterborne pathogens in biofilms may have entered the distribution system as fecal contamination from humans or animals.

Co-occurrence of indicators and waterborne pathogens is difficult to measure. While the analytical methods approved by EPA to assay for *E. coli* are able to detect indicators of fecal contamination, they do not specifically identify most of the pathogenic *E. coli* strains. There are at least 700 recognized *E. coli* strains (Kaper *et al.* 2004) and about 10 percent of recognized *E. coli* strains are pathogenic to humans (Feng 1995; Hussein 2007; Kaper *et al.* 2004). Pathogenic *E. coli* include *E. coli* O157:H7, which is the primary cause of HUS in the United States (Rangel *et al.* 2005). The US Centers for Disease Control and Prevention (CDC) estimates that there are 73,000 cases of illness each year in the US due to *E. coli* O157:H7 (Mead *et al.* 1999). The CDC estimates that about 15 percent of all reported *E. coli* O157:H7 cases are due to water contamination (Rangel *et al.* 2005). Active surveillance by CDC shows that 6.3 percent of *E. coli* O157:H7 cases progress to HUS (Griffin and Tauxe 1991; Gould *et al.* 2009) and about 12 percent of HUS cases result in death within four years (Garg *et al.* 2003). About 4 to 15 percent of cases are transmitted within households by secondary transmission (Parry and Salmon 1998).

Because EPA-approved standard methods for *E. coli* do not typically identify the presence of the pathogenic *E. coli* strains, an *E. coli*-positive monitoring result is an indicator of fecal contamination but is not necessarily a measure of waterborne pathogen occurrence. Specialized assays and methods are used to identify waterborne pathogens, including pathogenic *E. coli*.

One notable exception is the data reported by Cooley *et al.* (2007), which showed high concentrations of pathogenic *E. coli* strains in samples containing high concentrations of fecal indicator *E. coli*. These data are from streams and other poor quality surface waters surrounding

California spinach fields associated with the 2006 *E. coli* O157:H7 foodborne outbreak. Data equivalent to these samples are not available from drinking water samples collected under the 1989 TCR.

Because *E. coli* is an indicator of fecal contamination (Edberg *et al.* 2000), and because of the general association between fecal contamination and waterborne pathogens (Lieberman *et al.* 1994; Lieberman *et al.* 2002), *E. coli* is a meaningful indicator for fecal contamination and the potential presence of associated pathogen occurrence.

b. Waterborne disease outbreaks. The CDC defines a waterborne disease outbreak as occurring when at least two persons experience a similar illness after ingesting a specific drinking water (or after exposure to recreational water) contaminated with pathogens (or chemicals) (Kramer *et al.* 1996), or when one person experiences amoebic meningoencephalitis after similar waterborne exposure. The CDC maintains a database on waterborne disease outbreaks in the United States. The database is based upon responses to a voluntary and confidential survey form that is completed by State and local public health officials.

The National Research Council strongly suggests that the number of identified and reported outbreaks in the CDC database for surface and ground waters represents only a small percentage of the actual number of waterborne disease outbreaks (NRC 1997; Bennett *et al.* 1987; Hopkins *et al.* 1985 for Colorado data). Under-reporting occurs because most waterborne outbreaks in community water systems are not recognized until a sizable proportion of the population is ill (Perz *et al.* 1998; Craun 1996), perhaps 1 percent to 2 percent of the population (Craun 1996). EPA drinking water regulations are designed to protect against endemic waterborne disease and to minimize waterborne outbreaks. In contrast to outbreaks, endemic disease refers to the

persistent low to moderate level or the usual ongoing occurrence of illness in a given population or geographic area (Craun *et al.* 2006).

III. Requirements of the Revised Total Coliform Rule

The RTCR maintains and strengthens the objectives of the 1989 TCR and is consistent with the recommendations in the AIP. The objectives are: (1) to evaluate the effectiveness of treatment, (2) to determine the integrity of the distribution system, and (3) to signal the possible presence of fecal contamination. The RTCR better addresses these objectives by requiring systems that may be vulnerable to fecal contamination (as indicated by their monitoring results) to do an assessment, to identify whether any sanitary defect(s) is (are) present, and to correct the defects. Therefore, the Agency anticipates greater public health protection under the RTCR compared to the 1989 TCR because of its more preventive approach to identifying and fixing problems that affect or may affect public health. The following is an overview of the key provisions of the RTCR:

- *MCLG and MCL for E. coli and coliform treatment technique for protection against potential fecal contamination.* The RTCR establishes a maximum contaminant level goal (MCLG) and maximum contaminant level (MCL) for *E. coli*. Under the RTCR there is no longer a monthly maximum contaminant level (MCL) violation for multiple total coliform detections. The RTCR takes a preventive approach to protecting public health by establishing a coliform treatment technique for protection against potential fecal contamination. The treatment technique uses both total coliforms and *E. coli* monitoring results to start an evaluation process that, where necessary, requires the PWS to conduct follow-up corrective action that could prevent future incidences of contamination and exposure to fecal contamination and/or waterborne pathogens. See section III.B of this preamble, *Rule Construct: MCLG and MCL for E. coli and Coliform*

Treatment Technique, for further discussion on the MCLG, MCL, and treatment technique requirements.

- *Monitoring.* As with the 1989 TCR, PWSs will continue to monitor for total coliforms and *E. coli* according to a sample siting plan and schedule specific to the system.

Sample siting plans under the RTCR must continue to be representative of the water throughout the distribution system. Under the RTCR, systems have the flexibility to propose repeat sample locations that best verify and determine the extent of potential contamination of the distribution system rather than having to sample within five connections upstream and downstream of the total coliform-positive sample location. In lieu of proposing new repeat sample locations, the systems may stay with the default used under the 1989 TCR of within-five-connections-upstream-and-downstream of the total coliform-positive sample location.

As with the 1989 TCR, the RTCR allows reduced monitoring for some small ground water systems. The RTCR is expected to improve public health protection compared to the 1989 TCR by requiring small ground water systems that are on or wish to conduct reduced monitoring to meet certain eligibility criteria. Examples of the criteria include a sanitary survey showing that the system is free of sanitary defects, a clean compliance history for 12 months, and a recurring annual site visit by the State and/or a voluntary Level 2 assessment for systems on annual monitoring.

For small ground water systems, the RTCR requires increased monitoring for high-risk systems such as those that do not have a clean compliance history under the RTCR. The RTCR specifies conditions under which systems will no longer be eligible for reduced monitoring and be required to return to routine monitoring or to monitor at an increased frequency.

The RTCR requires systems on a quarterly or annual monitoring frequency (applicable only to ground water systems serving 1,000 or fewer people) to collect at least three additional routine monitoring samples the month following one or more total coliform-positive samples, unless the State waives the additional routine monitoring. This is a reduction in the required number of additional routine samples from the 1989 TCR, which requires at least five routine samples in the month following a total coliform-positive sample for all systems serving 4,100 or fewer people.

The 1989 TCR requires all systems serving 1,000 or fewer people to collect at least four repeat samples while requiring PWSs serving 1,000 people or greater to collect three repeat samples. The RTCR requires three repeat samples after a routine total coliform-positive sample, regardless of the system type and size.

See sections III.C, *Monitoring*, and III.D, *Repeat Samples*, of this preamble for detailed discussions of the routine monitoring and repeat sampling requirements of the RTCR.

- *Seasonal systems.* For the first time, the RTCR establishes monitoring requirements specific to seasonal systems. Seasonal systems represent a special case in that the shutdown and start-up of these water systems present additional opportunities for contamination to enter or spread through the distribution system. Under the RTCR, seasonal systems must demonstrate completion of a State-approved start-up procedure. See sections III.A.4, *Seasonal systems*, and III.C.1.f, *Seasonal systems*, of this preamble for further discussion of requirements for seasonal systems.
- *Assessment and corrective action.* As part of a treatment technique, all PWSs are required to assess their systems when monitoring results show that the system may be vulnerable to contamination. Systems must conduct either a Level 1 assessment or a more detailed Level 2 assessment depending on the level of concern raised by the results of indicator sampling. The

system is responsible for correcting any sanitary defect(s) found through either a Level 1 or Level 2 assessment. See section III.E of this preamble, *Coliform Treatment Technique*, for more discussion of the treatment technique requirement of the RTCR.

- *Violations and public notification.* The RTCR establishes an *E. coli* MCL violation, a treatment technique violation, a monitoring violation, and a reporting violation. Public notification is required for each type of violation, with the type of notification dependent on the degree of potential public health concern. This is consistent with EPA's current public notification requirements under 40 CFR part 141 subpart Q. The RTCR also modifies the public notification and Consumer Confidence Report language to reflect the construct of the rule. See sections III.F, *Violations*, and III.G, *Providing Notification and Information to the Public*, of this preamble for further discussions of violations and public notification under the RTCR.

- *Transition to the RTCR.* The RTCR allows all systems to transition to the new rule at their 1989 TCR monitoring frequency, including systems on reduced monitoring under the 1989 TCR. For ground water systems serving 1,000 or fewer people, States must conduct a special monitoring evaluation during each sanitary survey after the compliance effective date of the RTCR. Initial grandfathering of monitoring frequencies reduces State burden by not requiring the State to determine appropriate monitoring frequency at the same time the State is working to adopt primacy, develop policies, and train their own staff and the PWSs in the State.

The provisions of the RTCR are contained in the new 40 CFR part 141 subpart Y, superseding 40 CFR 141.21 beginning April 1, 2016.

A. *RTCR Definitions*

1. Assessment

a. Provisions. EPA is defining a Level 1 assessment and a Level 2 assessment to help in the implementation of the RTCR and to better differentiate between the two levels of assessments.

A Level 1 assessment is an evaluation to identify the possible presence of sanitary defects, defects in distribution system coliform monitoring practices, and (when possible) the likely reason that the system triggered the assessment. It is conducted by the system operator or owner (or his designated representative). Minimum elements include review and identification of atypical events that could affect distributed water quality or indicate that distributed water quality was impaired; changes in distribution system maintenance and operation that could affect distributed water quality (including water storage); source and treatment considerations that bear on distributed water quality, where appropriate (e.g., whether a ground water system is disinfected); existing water quality monitoring data; and inadequacies in sample sites, sampling protocol, and sample processing. The system must conduct the assessment consistent with any State directives that tailor specific assessment elements with respect to the size and type of the system and the size, type, and characteristics of the distribution system.

A Level 2 assessment is an evaluation to identify the possible presence of sanitary defects, defects in distribution system coliform monitoring practices, and (when possible) the likely reason that the system triggered the assessment. A Level 2 assessment provides a more detailed examination of the system (including the system's monitoring and operational practices) than does a Level 1 assessment through the use of more comprehensive investigation and review of available information, additional internal and external resources, and other relevant practices. It is conducted by an individual approved by the State, which may include the system operator. Minimum elements include review and identification of atypical events that could affect distributed water quality or indicate that distributed water quality was impaired; changes in

distribution system maintenance and operation that could affect distributed water quality (including water storage); source and treatment considerations that bear on distributed water quality, where appropriate (e.g., whether a ground water system is disinfected); existing water quality monitoring data; and inadequacies in sample sites, sampling protocol, and sample processing. The system must conduct the assessment consistent with any State directives that tailor specific assessment elements with respect to the size and type of the system and the size, type, and characteristics of the distribution system. The system must comply with any expedited actions or additional actions required by the State in the case of an *E. coli* MCL violation.

b. Key issues raised. EPA did not propose definitions for Level 1 and Level 2 assessments. However, based on the comments EPA received, there was concern that the distinction between the two levels of assessment is not sufficiently laid out in the rule language. This might pose some problems in the implementation of the RTCR. In response, EPA is defining a Level 1 assessment and a Level 2 assessment. This issue and the RTCR requirements regarding assessments are discussed further in section III.E.2 of this preamble, *Assessment*.

2. Clean compliance history

a. Provisions. In the final RTCR, EPA is defining “clean compliance history” as a record of no maximum contaminant level (MCL) violations under 40 CFR 141.63; no monitoring violations under 40 CFR 141.21 or subpart Y; and no coliform treatment technique trigger exceedances or coliform treatment technique violations under subpart Y. This is the same definition that the advisory committee recommended in the AIP and that EPA proposed in July 2010 (USEPA 2010a, 75 FR 40926, July 14, 2010). The term is specific to RTCR compliance and is used to determine eligibility of systems for reduced monitoring. It does not include violations under other existing NPDWRs. Systems must have a “clean compliance history” for a

minimum of 12 months to qualify for reduced monitoring (see sections III.C.1.b.iii, *Reduced monitoring*, and III.C.1.c.iii, *Reduced monitoring*, of this preamble regarding reduced monitoring).

However, while the definition of “clean compliance history” includes only 1989 TCR/RTCR violations, the State may (and should) consider compliance history under other rules if relevant. For example, failure to take a triggered source water sample required under the GWR (USEPA 2006, 71 FR 65574, November 8, 2006) may appropriately cause the State to not allow less frequent monitoring because this could (1) lead the system to miss source water contamination and (2) indicate a system’s lack of attention to regulatory requirements or proper operation.

b. Key issues raised. EPA received comments that a record of no monitoring violations should not be included in the definition of “clean compliance history.” Commenters are concerned that small systems, which experience frequent turnover or shortage of staff, may not be able to qualify for reduced monitoring if they miss a sample or two. EPA believes that a system on a reduced monitoring frequency (i.e., less than monthly, either quarterly or annually) must be able to demonstrate that it is capable of delivering safe water and maintaining proper attention to the water system, even on an infrequent monitoring schedule, by meeting certain criteria (see sections III.C.1.b.iii, *Reduced monitoring*, and III.C.1.c.iii, *Reduced monitoring*, of this preamble for discussion about the reduced monitoring criteria). Small systems monitoring less frequently than monthly, especially those monitoring only annually, already have a lower probability of detecting a contamination event compared to systems that monitor monthly. Because of the intermittent nature of contamination and the fact that these systems are already on a significantly reduced monitoring frequency, it is very important that these systems take their samples as required. Because these systems monitor so infrequently, EPA recommends that the

States use the annual site visits as an opportunity to review system operations, reinforce the importance of collecting the required samples, and to identify and require correction of any sanitary defects. The State can make sure that the system takes its required sample, and therefore avoids incurring a monitoring violation because of a missed sample (see section III.C.1.b.iii of this preamble, *Reduced monitoring*, for discussion of annual monitoring). EPA is therefore retaining the definition of “clean compliance history” as proposed because EPA believes that removing the record of no monitoring violation from the definition would be less protective of public health. However, EPA is providing flexibility to the States in considering monitoring violations in TNCWSs when determining whether the system must go on increased monthly monitoring. See sections III.C.1.b, *Ground water NCWSs serving ≤ 1,000 people*, and III.C.2.b, *Ground water NCWSs serving ≤ 1,000 people*, of this preamble for a more detailed discussion.

3. Sanitary defect

a. Provisions. EPA is finalizing the definition of sanitary defect as proposed in July 2010 (USEPA 2010a, 75 FR 40926, July 14, 2010). It is defined as a “defect that could provide a pathway of entry for microbial contamination into the distribution system or that is indicative of a failure or imminent failure in a barrier that is already in place.” As stated in the proposed rule, the first part of the definition focuses on the problems in the distribution system that may provide a pathway for contaminants to enter the distribution system and its implication for potential exposure to both microbial and chemical contaminants. The second part of the definition also recognizes the importance of having barriers in place to prevent the entry of microbial contaminants into the distribution system. Indications of failure or imminent failure of these barriers are defects that require corrective action.

The advisory committee deliberated on the definition of sanitary defect and suggested that the definition should be broad enough to facilitate corrective action without absolute confirmation of cause and effect, as such confirmation may be impossible or may significantly delay corrections that would address a sanitary defect that represents a potential threat to public health. Conversely, the language is not intended to suggest that corrections must be undertaken where the linkage between the defect and public health is tenuous. The advisory committee also agreed that it is their intent that nothing in the definition of sanitary defects precludes conducting an assessment of every element on the example checklists for Level 1 and Level 2 assessments (USEPA 2008d).

b. Key issues raised. EPA received comments regarding the relationship between sanitary defects under the RTCR and “significant deficiencies” under other regulations and the possible confusion between the two terms. One commenter said that the requirement to identify and correct sanitary defects under the RTCR is very similar to the GWR’s requirement to identify and correct significant deficiencies, and that EPA should therefore consider which rule is more effective at minimizing risk of contamination.

The advisory committee specifically stated that “sanitary defects” are specific to the assessment and corrective action requirements of the RTCR and are not intended to be linked directly to “significant deficiencies” under the Interim Enhanced Surface Water Treatment Rule (IESWTR) (USEPA 1998, 63 FR 69389, December 16, 1998) and the GWR, although some problems could meet either definition. The term “significant deficiency” is tied or associated with the eight elements of a sanitary survey. There are problems that are “sanitary defects” and are also “significant deficiencies”. For instance, source water problems like those associated with the well casing may fit the definition of both a “sanitary defect” and a “significant

deficiency.” Depending on when the problem was identified (i.e., during a sanitary survey or during an assessment triggered under RTCR) and on the guidelines set by the State, the system should coordinate with their State regarding how to characterize the problem and how to coordinate the corrective action requirements under the GWR and RTCR, if needed. Conversely, there are problems that are “sanitary defects” but are not “significant deficiencies” and vice versa. “Significant deficiency” can include problems other than those in the distribution system that can have an effect on the long term viability of the system in delivering safe water to its customers. “Significant deficiencies” can also exist in the areas of reporting and data verification, system management and operation, and operator compliance with State requirements, which are not considered “sanitary defects.”

Furthermore, although there might be overlap between a “sanitary defect” and “significant deficiency,” there are differences in the required timeframes for responding to them (see 40 CFR 141.403(a)(5) and 142.16(b)(1)(ii), and §§ 141.859(b)(3) and (b)(4) of the RTCR). It might therefore be more confusing to use only one term for the requirements of the GWR and RTCR, as suggested by some commenters.

In addition, the GWR only applies to ground water systems. Relying only on the corrective action provisions of the GWR (triggered by a fecal indicator-positive sample) will leave out those systems not covered by the GWR. Also, these GWR provisions are focused on the source water. Since contamination is intermittent and can be from a location other than the source water, the assessment and corrective action provisions in the RTCR will help to better address other types of defects.

As noted in the preamble to the proposed RTCR, nothing in the RTCR is intended to limit the existing authorities of States under other regulations.

4. Seasonal systems

a. Provisions. EPA is finalizing the definition of seasonal system as “a non-community water system that is not operated on a year-round basis and starts up and shuts down at the beginning and end of each operating season.”

The advisory committee recognized that seasonal systems have unique characteristics that make them susceptible to contamination. As their name implies, seasonal systems are not operated year-round. The depressurizing and dewatering of the water system, as often occurs with the temporary shutdown of the system, present opportunities for contamination to enter or spread through the distribution system. For example, loss of pressure after a system’s shutdown can lead to intrusion of contaminants. Even a system that remains pressurized may be subject to water quality degradation due to stagnant water or loss of disinfectant residual. Microbial growth prior to start-up can result in biofilm formation, which can lead to the accumulation of contaminants. These systems are also more susceptible to contamination due to changes in the conditions of the source water (such as variable contaminant loading due to increased septic tank or septic field use), the seasonal nature of the demand, and the stress that the system experiences. As a result, the Agency is establishing a definition for seasonal systems and setting forth provisions that mitigate the risk associated with the unique characteristics of this type of system (see section III.C.1.f of this preamble, *Seasonal systems*, for requirements for seasonal systems). The advisory committee recommended that such provisions pertain to seasonal systems.

The definition of seasonal system that EPA is promulgating with this final rule is different from the definition proposed in July 2010 (USEPA 2010a, 75 FR 40926, July 14, 2010), which is “a non-community water system that is operated in three or fewer calendar quarters per calendar year.” As discussed in the preamble to the proposed rule, EPA was aware of the limitations of

the proposed definition that could lead to less public health protection and less effective and more complicated implementation. EPA gave the example of a system that is operated from March to October. Such a system would operate in all four calendar quarters and therefore would not be considered a seasonal system according to the proposed definition, but would nonetheless be subject to the same possibility of distribution system contamination as a seasonal system operated from April to November (i.e., in only three calendar quarters). To address limitations such as this, EPA specifically requested comment on the proposed definition of a seasonal system. The change in the definition from the proposed rule is based on the comments received. Specific requirements (e.g., monitoring, start-up procedure, etc.) for seasonal systems that address the issues associated with such systems are discussed in section III.C.1.f, *Seasonal systems*, and III.C.2.c, *Seasonal systems*, of this preamble.

The definition does not include intermittent systems, such as those that are open year-round but are not operated continuously (e.g., a church open only on Saturdays and Sundays). It also does not include systems that operate year-round but may shut down part of their distribution system for part of the year (e.g., parts of the distribution system that serve a factory that is open only certain times of the year). Since these systems might be subject to the same type of risks as seasonal systems, States may want to consider whether to establish requirements that will mitigate the risks associated with their operation.

b. Key issues raised. EPA received many responses regarding the definition of a seasonal system. Many commenters suggested addressing the issue of depressurization and dewatering in the definition. They suggested that the important risk factor is not the number of quarters the system is in operation but rather the closure and the depressurization and/or dewatering of the distribution system. Other commenters expressed concern about contamination associated with

lack of water movement and loss of disinfectant residual even in a pressurized system. Although the definition of seasonal systems does not directly address these issues, seasonal systems are required to perform start-up procedures (which may include disinfection, flushing, and coliform sampling) prior to serving water to the public. See section III.C.1.f of this preamble, *Seasonal systems*, for a discussion of the requirements for seasonal systems. EPA believes that it is important for a seasonal system to perform start-up procedures to mitigate the public health risks associated with stagnant water and the depressurization and/or dewatering of the distribution system. Hence, failure to perform start-up procedures will result in a treatment technique violation. See section III.F.b of this preamble, *Coliform treatment technique violation*, for additional discussion on this violation.

Since it is possible and perhaps likely that some systems may keep the distribution system pressurized while out of season, EPA has included an additional provision in the RTCR whereby a State can exempt any seasonal system from some or all of the requirements for seasonal systems if the entire distribution system remains pressurized during the entire period that the system is not operating (see §§ 141.854(i)(3), 141.856(a)(4)(ii), and 141.857(a)(4)(ii) of the RTCR). In providing such exemption, the State should conclude that public health protection is maintained. However, a seasonal system monitoring less frequently than monthly must still monitor during the vulnerable period designated by the State. See section III.C.1.f of this preamble, *Seasonal systems*, for additional discussion.

Some commenters suggested that seasonal systems be defined by the number of days, months, or quarters they are not in operation, e.g., 30, 60, or 90 consecutive days, three or more consecutive months, one full calendar quarter, etc. While such a change could address some of

EPA's concerns, it does not address the potential for contamination associated with lack of operation and loss of pressure.

B. Rule Construct: MCLG and MCL for E. coli and Coliform Treatment Technique

1. MCLG and MCL

a. Requirements. Under the final RTCR, EPA is eliminating the MCLG for total coliforms (including fecal coliforms) and the MCL for total coliforms. EPA is also establishing an MCLG of zero and an MCL for *E. coli*. The MCL for *E. coli* is based on the monitoring results for total coliforms and *E. coli*. A system is in compliance with the *E. coli* MCL unless any of the following conditions occur:

- A system has an *E. coli*-positive repeat sample following a total coliform-positive routine sample; or
- A routine sample is *E. coli*-positive and one of its associated repeat samples is total coliform-positive; or
- A system fails to test for *E. coli* when any repeat sample tests positive for total coliforms; or
- A system fails to take all required repeat samples following a routine sample that is positive for *E. coli*.

Although not explicitly stated, as a logical consequence of the second condition, a system also violates the MCL when an *E. coli*-positive routine sample is followed by an *E. coli*-positive repeat sample because *E. coli* bacteria are a subset of total coliforms.

EPA is establishing an MCLG of zero for *E. coli* and removing the current MCLG of zero for total coliforms (including fecal coliforms) because *E. coli* is a more specific indicator of fecal contamination and potential harmful pathogens in drinking water than are total coliforms (including fecal coliforms). These requirements were part of the July 2010 proposed rule

(USEPA 2010a, 75 FR 40926, July 14, 2010) and are unchanged in the final RTCR. See section III.A.2 of the preamble to the proposed RTCR, *MCLG and MCL for E. coli, and coliform treatment technique*, for further discussion on the MCLG, MCL, and treatment technique requirements.

b. Key issues raised. The majority of the commenters supported EPA's proposal to remove the MCLG and MCL for total coliforms (including fecal coliforms) and to establish an MCLG and MCL for *E. coli*.

However, there were some who commented that removing the MCLG and MCL for total coliforms will result in backsliding in public health protection. These commenters stated that the elimination of the non-acute MCL violation removes a strong incentive for water systems to perform proactive maintenance and operations activities to maintain distribution system water quality and avoid MCL violations and subsequent public notice to customers. EPA disagrees. EPA and the advisory committee decided that removing the MCLG and MCL for total coliforms is appropriate. SDWA section 1412(b)(3)(A)(i) directs EPA to use "the best available, peer-reviewed science and supporting studies conducted in accordance with sound and objective science practices" in conducting the risk assessment when promulgating an NPDWR. In 1989, EPA set an MCLG of zero for total coliforms. Since the promulgation of the 1989 TCR, a better understanding of the nature of total coliforms, especially fecal coliforms, has become available. Many of the organisms detected by total coliform and fecal coliform methods are not of fecal origin and do not have any direct public health implications (Edberg *et al.* 2000). Total coliforms may, however, indicate the presence of a pathway by which fecal contamination can occur; thus, total coliforms are instead used as part of a treatment technique requirement, which is discussed in more detail in the next section and in section III.E of this preamble, *Coliform*

Treatment Technique. Inclusion of the MCLG and MCL for total coliforms is not supported by the available science and would be contrary to SDWA section 1412(b)(3)(A)(i).

Commenters agreed with EPA's proposal to eliminate the provisions on fecal coliforms. Therefore, fecal coliforms will no longer be used in the RTCR and all analytical methods used to detect for fecal coliforms are also removed from the rule. For a discussion on analytical methods, see section III.I of this preamble, *Analytical Methods*.

2. Coliform treatment technique

a. Requirements. EPA is establishing a treatment technique that will require a PWS to conduct an assessment of its system and, when necessary, perform corrective actions in response to trigger conditions that indicate a possible pathway of contamination into the system. The treatment technique requirements are the same as those in the proposed RTCR. A PWS that exceeds a specified frequency of total coliform occurrence must conduct a Level 1 or Level 2 assessment to determine if any sanitary defect exists and, if found, to correct the sanitary defect. As discussed earlier, the MCLG and MCL for total coliforms are removed. The conditions that defined a non-acute MCL violation under the 1989 TCR are now used to trigger a system to conduct an assessment of the system. A discussion of the treatment technique requirements, i.e., the triggers, the levels of assessment, the completion of the assessment form, etc., can be found in section III.E of this preamble, *Coliform Treatment Technique*.

b. Key issues raised. The majority of the commenters supported the change from a total coliform non-acute MCL to a treatment technique requirement. However, some commenters disagreed with the change. They stated that the treatment technique construct will not work for small NCWSs since they typically do not treat their water, have no certified operator, and have limited or no distribution system. They noted that since systems with limited or no distribution

system do not have the extensive network of piping and service connections and other elements that comprise a typical distribution system, the treatment technique construct, which the commenters considered as focusing on the distribution system, will not work. These commenters suggested that for systems with limited or no distribution system, the focus should be on the source, and therefore, the requirements of the GWR should be sufficient. They suggested that the total coliform MCL should be retained for these systems because the treatment technique requirements will be too complicated for these systems to comply with, resulting in more non-compliance, more burden on the State, and likely less public health protection.

EPA disagrees that the treatment technique construct will not work for small NCWSs. The requirement to assess the system after a trigger consists of looking at all of the elements that might have affected the quality of the distributed water, including not only the distribution system but also the source and the treatment process. Although some small systems have limited or no distribution system, they can still have parts of their system (e.g., building plumbing, or buried piping at a campground) that are vulnerable to contamination, such as that introduced by a cross-connection or infiltration. In addition, relying only on the corrective action provisions of the GWR will leave out those systems not covered by the GWR, or in cases of positive results, systems where corrective action under the GWR is not immediately required by the State. For example, total coliform-positive repeat samples do not trigger any action under the GWR, even if those samples are also triggered source water samples. Also, a State may require additional source samples instead of a corrective action after the first fecal indicator positive sample (see 40 CFR 141.402(a)(3)). In addition, some small NCWSs with limited or no distribution system use surface water. Finally, the GWR provisions are focused on the source water. Since

contamination is intermittent and can be from a location other than the source water, the assessment and corrective action provisions in the RTCR will help address other types of defects.

EPA understands that there will be implementation challenges during the first few years of the rule implementation, especially for small PWSs. However, as systems with limited or no distribution system are simple systems, the assessments should also be relatively simple. There is nothing in the RTCR that prohibits the States from conducting assessments that integrate the requirements of the GWR and RTCR where appropriate (see section III.E of this preamble, *Coliform Treatment Technique*, for a discussion of the coliform treatment technique). EPA encourages States to make any necessary modifications to their regulations to make the most efficient use of limited State resources and to better integrate these rules for systems with little-to-no distribution system, provided that the revisions satisfy the primacy requirements for both the GWR and the RTCR. Also, EPA plans to develop guidance manuals specifically for small systems to help them comply with the RTCR. EPA is also working to update the Safe Drinking Water Information System (SDWIS) to include the requirements of the RTCR and have SDWIS ready in advance of the compliance date for the rule.

As discussed earlier, EPA believes that the treatment technique requirements are more protective of public health because they require a system to take preventive actions to address problems. This is a change from just issuing a PN and conducting additional monitoring under the 1989 TCR to proactively doing an assessment to determine the cause of the possible contamination under the RTCR and performing corrective action where needed.

C. Monitoring

1. Requirements

a. *Requirements that apply to all PWSs.* As with the 1989 TCR, the RTCR requires all PWSs to collect and test samples for total coliforms and *E. coli* according to a sample siting plan and schedule specific to the system. PWSs must collect the samples at regular intervals throughout the month, except systems that use only ground water and serve 4,900 or fewer people may collect all required samples on a single day if they are taken from different sites.

Under the RTCR, all PWSs are still required to take repeat samples within 24 hours of learning of any routine monitoring sample that is total coliform-positive. PWSs must comply with the repeat monitoring requirements and *E. coli* analytical requirement, discussed in detail in section III.D of this preamble, *Repeat Samples*. All samples taken for RTCR compliance (routine and repeat) may occur at a customer's premises, dedicated sampling station, or other designated compliance sampling location.

EPA notes that a system must still take the required minimum number of samples even if it has had an *E. coli* MCL violation or has exceeded the coliform treatment triggers before the end of the monitoring compliance period. For example, if a system has an *E. coli* MCL violation after taking 10 of the 40 required routine monthly samples, the system must continue routine total coliform monitoring, analyze any total coliform-positive samples for *E. coli*, and take one round of repeat samples following any total coliform-positive routine sample.

Under the RTCR, systems' sample siting plans must include routine and repeat sample sites and any sampling points necessary to meet the Ground Water Rule (GWR) requirements. As with the 1989 TCR, the sample siting plan is subject to State review and revision.

The repeat sample sites may be alternative monitoring locations that the PWS is proposing to use instead of the repeat sample locations that are within five connections upstream and downstream of the original sampling location that tested total coliform-positive. The PWS must

demonstrate to the State's satisfaction that the alternative monitoring locations are representative of a pathway for contamination into the distribution system (for example, near a storage tank), and that the sample siting plan remains representative of the water quality in the distribution system. Systems may elect to specify either alternative fixed locations or criteria for selecting their repeat sampling locations on a situational basis in a standard operating procedure (SOP), which is part of the sample siting plan. The State may determine that monitoring at the entry point to the distribution system (especially for undisinfected ground water systems) is effective to differentiate between potential source water and distribution problems. The use of alternative monitoring locations or an SOP does not require prior State approval but systems are required to submit to their primacy agencies their proposed alternative locations. States can modify and revise these locations or the SOP as needed. Additional discussion about the alternative monitoring locations can be found in section III.D of this preamble, *Repeat Samples*.

Monitoring locations that serve both as a repeat sampling location and a triggered source water monitoring location for the GWR (i.e., locations for dual purpose sampling) must also be included in the sample siting plan. These locations need to be approved by the State before the PWS can use them. For more discussion on the dual purpose sampling, see section III.D of this preamble, *Repeat Samples*.

Under the RTCR, PWSs may take more than the minimum required number of routine samples and must include the results in calculating whether the total coliform treatment technique trigger for conducting an assessment has been exceeded, but only if the samples are taken in accordance with the sample siting plan and are representative of water throughout the distribution system (see section III.E of this preamble, *Coliform Treatment Technique*, for a discussion on the coliform treatment technique requirements).

Under the RTCR, EPA is not making substantive changes to the requirements of the TCR for (1) special purpose samples, and (2) invalidation of total coliform samples.

New systems that begin operation on or after the compliance date of the RTCR must comply with the routine monitoring frequency established by the RTCR for their system size and type beginning in their first month of operation.

The following are the monitoring requirements for different categories of systems.

b. Ground water NCWSs serving $\leq 1,000$ people. i. Routine monitoring. The RTCR requires ground water NCWS serving 1,000 or fewer people to routinely monitor each quarter for total coliforms and *E. coli* except that systems can transition into RTCR at their 1989 TCR monitoring frequency as discussed in further detail in the next section, and there are provisions under which the monitoring frequency may be reduced or increased. Seasonal systems under this category must routinely monitor every month that they are in operation (see section III.C.1.f of this preamble, *Seasonal systems*, for additional discussion on seasonal system requirements).

ii. Transition to the RTCR. The RTCR requires all ground water NCWSs serving 1,000 or fewer people, including seasonal systems, to continue with their 1989 TCR monitoring schedules as of the compliance date of the RTCR, unless or until any of the conditions for increased monitoring discussed later in this section are triggered on or after the compliance date, or unless otherwise directed by the State as a result of the special monitoring evaluation conducted under a sanitary survey or at any other time the State believes that the sampling the system is conducting may not be adequate. In addition, systems on annual monitoring, including seasonal systems, must have an initial annual site visit by the State within one year of the compliance date and an annual site visit each calendar year thereafter to remain on annual monitoring. Systems may substitute a voluntary Level 2 assessment by a party approved by the State for the annual site

visit in any given year. The periodic sanitary survey may be used to meet the requirement for an annual site visit for the year in which the sanitary survey was completed.

After the compliance date of the final RTCR, during each sanitary survey the State must perform a special monitoring evaluation to review the status of the water system, including the distribution system, to determine whether the system is on an appropriate RTCR monitoring schedule and modify the monitoring schedule as necessary. States must evaluate system factors such as the pertinent water quality and compliance history, the establishment and maintenance of contamination barriers, and other appropriate protections, and validate the appropriateness of the water system's existing RTCR monitoring schedule and modify as necessary. For seasonal systems on quarterly or annual monitoring, this evaluation must also include review of the approved sample siting plan, which designates the time period(s) for monitoring based on site-specific considerations (such as during periods of highest demand or highest vulnerability to contamination). The system must collect compliance samples during these designated time periods.

iii. Reduced monitoring. The State has the discretion to reduce the monitoring frequency for well-operated ground water NCWSs from the quarterly routine monitoring to no less than annual monitoring, if the water system can demonstrate that it meets the criteria for reduced monitoring provided in this section.

To be eligible to qualify for and remain on annual monitoring after the compliance date, a ground water NCWS serving 1,000 or fewer people must meet all of the following criteria:

- The system must have a clean compliance history (no MCL violations or monitoring violations under the 1989 TCR and/or RTCR, no Level 1 or Level 2 trigger exceedances or treatment technique violations under the RTCR) for a minimum of 12 months. (For a more

detailed discussion on Level 1 and Level 2 triggers, see section III.E of this preamble, *Coliform Treatment Technique*);

- The most recent sanitary survey shows the system is free of sanitary defects, has a protected water source and meets approved construction standards; and
- An initial site visit by the State within the last 12 months to qualify for reduced annual monitoring, and recurring annual site visits to stay on reduced annual monitoring; and correction of all identified sanitary defects. A voluntary Level 2 assessment by a party approved by the State may be substituted for the State annual site visit in any given year.

iv. Increased monitoring. Ground water NCWS serving 1,000 or fewer people on quarterly or annual monitoring must begin monthly monitoring the month after any of the following events occurs:

- The system triggers a Level 2 assessment or two Level 1 assessments in a rolling 12 month period;
- The system has an *E. coli* MCL violation;
- The system has a coliform treatment technique violation (for example, if the system fails to conduct a Level 1 assessment or correct for sanitary defects if required to do so);
- The system on quarterly monitoring has two RTCR monitoring violations; or
- The system has one RTCR monitoring violation and triggers a Level 1 assessment in a rolling 12-month period.

EPA added the last condition by which a ground water NCWS serving $\leq 1,000$ people can be triggered into increased monitoring to improve the internal consistency of these triggers, given that these NCWSs monitor less frequently in general, and given the added flexibility for States to elect not to count monitoring violations at TNCWS toward triggers to increased monitoring as

described in the next paragraph. Since either two Level 1 assessments or two RTCR monitoring violations in a rolling 12-month period triggers increased monitoring, EPA believes it is appropriate for one of each of these events to also trigger increased monitoring for these NCWSs. See section III.E.1 of this preamble, *Coliform treatment technique triggers*, for a discussion of coliform treatment technique triggers.

EPA also added flexibility to allow States to elect to not count TNCWS monitoring violations in determining whether the trigger for increased monitoring has been exceeded, but only if the missed sample is collected no later than the end of the next monitoring period. The system must collect the make-up sample in a different week than the routine sample for the next monitoring period and should collect the sample as soon as possible during the next monitoring period. This provision applies only for routine samples. The TNCWS would still incur a monitoring violation and must follow the other requirements associated with such violation (e.g., public notification and reporting). This provision is added in response to comments received by EPA. See section III.C.2.b of this preamble, *Ground water NCWSs serving $\leq 1,000$ people*, for additional discussion of this provision.

Ground water NCWS serving 1,000 or fewer people on annual monitoring must begin quarterly monitoring the month after the following event occurs:

- The system on annual monitoring has one RTCR monitoring violation.

This is a change from the proposed rule requirement where the event would have triggered the system to go to monthly monitoring instead of quarterly monitoring. This change is further discussed in section III.C.2.b of this preamble, *Ground water NCWSs serving $\leq 1,000$ people*.

The system must continue monthly or quarterly monitoring until the requirements in this section for returning to quarterly or annual monitoring are met.

v. Requirements for returning to quarterly monitoring. To be eligible to return from increased monthly monitoring to quarterly monitoring, ground water NCWSs serving 1,000 or fewer people must meet all of the following criteria:

- Within the last 12 months, the system must have a completed sanitary survey or a site visit by the State or a voluntary Level 2 assessment by a party approved by the State. The system is free of sanitary defects, and has a protected water source; and
- The system has a clean RTCR compliance history (no *E. coli* MCL violations, Level 1 or 2 triggers, coliform treatment technique violations or monitoring violations) for a minimum of 12 months.

For TNCWSs, the State may elect not to count monitoring violations towards the requirement of a clean compliance history (as presented in the last bullet) if the missed sample is collected no later than the end of the next monitoring period. This applies only for routine samples. The TNCWS would still incur a monitoring violation and must follow the other requirements associated with such violation (e.g., public notification and reporting). See section III.C.2.b of this preamble, *Ground water NCWSs serving $\leq 1,000$ people*, for additional discussion about this provision.

vi. Requirements for returning to reduced annual monitoring. To be eligible to return from increased monthly monitoring to reduced annual monitoring, the system must meet the criteria to return to routine quarterly monitoring plus the following criteria:

- An annual site visit (recurring) by the State and correction of all identified sanitary defects. An annual voluntary Level 2 assessment may be substituted for the State annual site visit in any given year; and

- The system must have in place or adopt one or more additional enhancements to the water system barriers to contamination as approved by the State. These measures could include but are not limited to the following:
 - Cross connection control, as approved by the State.
 - An operator certified by an appropriate State certification program, which may include regular visits by a circuit rider certified by an appropriate State certification program.
 - Continuous disinfection entering the distribution system and a residual in the distribution system in accordance with criteria specified by the State.
 - Maintenance of at least a 4-log inactivation or removal of viruses each day of the month based on daily monitoring as specified in the GWR (with allowance for a 4-hour exception).
 - Other equivalent enhancements to water system barriers to contamination as approved by the State.

vii. Additional routine monitoring. All systems collecting samples on a quarterly or annual frequency must conduct additional routine monitoring following a single total coliform-positive sample (with or without a Level 1 trigger event). The additional routine monitoring consists of three samples in the month following the total coliform-positive sample at routine monitoring locations identified in the sample siting plan. This is a change from the 1989 TCR additional routine monitoring requirement of taking a total of five samples the month following a total coliform-positive sample for systems that take four or fewer samples per month. Consistent with the 1989 TCR, the State may waive the additional routine monitoring requirement if:

- The State, or an agent approved by the State, performs a site visit before the end of the next month the system provides water to the public. Although a sanitary survey need not be

performed, the site visit must be sufficiently detailed to allow the State to determine whether additional monitoring and/or any corrective action is needed. The State cannot approve an employee of the system to perform this site visit, even if the employee is an agent approved by the State to perform sanitary surveys or RTCR assessments.

- The State has determined why the sample was total coliform-positive and establishes that the system has corrected the problem or will correct the problem before the end of the next month the system serves water to the public. In this case, the State must document this decision to waive the following month's additional monitoring requirement in writing, have it approved and signed by the supervisor of the State official who recommends such a decision, and make this document available to the EPA and public. The written documentation must describe the specific cause of the total coliform-positive sample and what action the system has taken and/or will take to correct this problem.
- The State may not waive the requirement to collect three additional routine samples the next month in which the system provides water to the public solely on the grounds that all repeat samples are total coliform-negative. If the State determines that the system has corrected the contamination problem before the system takes the set of repeat samples required in § 141.858, and all repeat samples were total coliform-negative, the State may waive the requirement for additional routine monitoring the next month.

All additional routine samples are included in determining compliance with the MCL and coliform treatment technique requirements.

c. Ground water CWSs serving $\leq 1,000$ people. i. Routine monitoring. The RTCR requires ground water CWSs serving 1,000 or fewer people to routinely monitor at least once each month for total coliforms and *E. coli* except that systems can transition into RTCR at their 1989 TCR

monitoring frequency as discussed in further detail in the next section, and there are provisions under which the sampling frequency may be reduced by the State.

The State may reduce the monitoring frequency for ground water CWS from the monthly routine monitoring to quarterly reduced monitoring if the water system can demonstrate that it meets the criteria for reduced monitoring provided later in this section.

ii. Transition to the RTCR. All ground water CWSs serving 1,000 or fewer people continue with their 1989 TCR monitoring schedules unless or until any of the increased monitoring requirements in this section occur or as directed by the State.

After the compliance date of the final RTCR, the State must determine whether the system is on an appropriate monitoring schedule by performing a special monitoring evaluation during each sanitary survey to review the status of the PWS, including the distribution system. The first such evaluation must be conducted during the first scheduled sanitary survey after the effective date of the rule; a system may remain on its 1989 TCR monitoring schedule until this time unless it is triggered into more frequent monitoring. After its first evaluation, the State may allow the system to remain on its 1989 TCR monitoring schedule as long as the system meets the conditions for doing so. The State must evaluate system factors such as the pertinent water quality and compliance history, the establishment and maintenance of barriers to contamination, and other appropriate protections to validate the water system's existing monitoring schedule or require more frequent monitoring.

iii. Reduced monitoring. The State has the flexibility to reduce the monitoring frequency for well-operated ground water CWS from the monthly routine monitoring to no less than quarterly monitoring if the water system can demonstrate that it meets the criteria for reduced monitoring provided in this section.

To be eligible to change from monthly to quarterly reduced monitoring after the compliance date, ground water CWSs serving 1,000 or fewer people must be in compliance with any State-certified operator provisions and meet each of the following criteria:

- The system must have a clean compliance history (no MCL violations or monitoring violations under the TCR and/or RTCR, no Level 1 or Level 2 trigger exceedances or treatment technique violations under the RTCR) for a minimum of 12 months;
- The most recent sanitary survey shows the system is free of sanitary defects (or has an approved plan and schedule to correct them and is in compliance with the plan and the schedule), has a protected water source, and meets approved construction standards; and
- The system must meet at least one of the following criteria:
 - An annual site visit by the State or an annual voluntary Level 2 assessment by a party approved by the State or meeting criteria established by the State and correction of all identified sanitary defects (or an approved plan and schedule to correct them and is in compliance with the plan and schedule).
 - A cross connection control program, as approved by the State.
 - Continuous disinfection entering the distribution system and a residual in the distribution system in accordance with criteria specified by the State.
 - Demonstration of maintenance of at least a 4-log inactivation or removal of viruses each day of the month based on daily monitoring as specified in the GWR (with allowance for a 4-hour exception) (USEPA 2006c, 71 FR 65574, November 8, 2006).
 - Other equivalent enhancements to water system barriers to contamination as approved by the State.

iv. Requirements for returning to monthly monitoring. When a system on quarterly monitoring experiences any of the following events the system must begin monthly monitoring the month after the event occurs:

- System triggers a Level 2 assessment or two Level 1 assessments in a rolling 12-month period.
- System has an *E. coli* MCL violation.
- System has a coliform treatment technique violation (e.g., fails to conduct a Level 1 or Level 2 assessment or to correct for a sanitary defect if required to do so).
- System has two routine RTCR monitoring violations in a rolling 12-month period.

The system must continue monthly monitoring until all the reduced monitoring requirements discussed previously in this section are met. A system that loses its certified operator must also return to monthly monitoring the month following the loss.

v. Additional routine monitoring. Ground water CWSs serving $\leq 1,000$ people collecting samples on a quarterly frequency must conduct additional routine monitoring following a single total coliform-positive sample (with or without a Level 1 trigger event), similar to the additional monitoring requirements for ground water NCWS serving $\leq 1,000$ people. See section III.C.1.b.vii of this preamble, *Additional routine monitoring*, for a discussion of the additional routine monitoring requirements.

d. *Subpart H systems serving $\leq 1,000$ people.* The monitoring requirements for subpart H systems of this part (PWSs supplied by a surface water source or by a ground water under the direct influence of surface water (GWUDI) source) serving 1,000 or fewer people remain the same as under the 1989 TCR (see § 141.856). These systems are not eligible for reduced monitoring. In addition, the rule requires all seasonal systems, on and after the compliance date

of the final RTCR, to demonstrate completion of a State-approved start-up procedure (see section III.C.1.f of this preamble, *Seasonal systems*, for additional discussion on seasonal system requirements).

e. PWSs serving > 1,000 people. The monitoring requirements for PWSs serving more than 1,000 people remain the same as under the 1989 TCR (see § 141.857), with the exception of the applicable revisions to the repeat sampling locations provided in § 141.858 and to the additional routine monitoring provisions. Systems on monthly monitoring are not required to take additional routine samples the month following a total coliform-positive sample, as recommended by the advisory committee (see section III.A.3.b.ii(g) of the preamble to the proposed RTCR, *Additional routine monitoring*, for an explanation of this change from the 1989 TCR). Consistent with the 1989 TCR, systems serving > 1,000 people are not eligible for reduced monitoring. In addition, the rule requires all seasonal systems, on and after the compliance date of the final RTCR, to demonstrate completion of a State-approved start-up procedure (see section III.C.1.f of this preamble, *Seasonal systems*, for additional discussion on seasonal system requirements).

f. Seasonal systems. Since seasonal systems are a subset of NCWSs, they are subject to the requirements of the particular NCWS size category they fall under (e.g., seasonal systems using ground water and serving $\leq 1,000$ people are subject to the requirements of ground water NCWS serving $\leq 1,000$ people, or seasonal systems using surface water and serving $\leq 1,000$ people are subject to the requirements of subpart H systems serving $\leq 1,000$ people, and so on), unless otherwise noted. The RTCR is promulgating requirements specific to seasonal systems to mitigate the risk associated with the unique characteristics of this type of systems (see section III.A.4 of this preamble, *Seasonal systems*, for additional discussion about seasonal systems).

One of the provisions is the requirement that all seasonal systems must demonstrate completion of a State-approved start-up procedure prior to serving water to the public on and after the compliance date of the final RTCR each time they start up the system. The start-up procedure may include a requirement for a start-up sample prior to serving water to the public.

Under the RTCR, all seasonal systems are required to take at least one routine sample per month for total coliforms and *E. coli* during the months that they are in operation, unless the sampling frequency has been reduced by the State under the RTCR. Seasonal systems serving > 1,000 people have the same monitoring frequency as other PWSs serving > 1,000 people (see § 141.857 of the RTCR) and it cannot be reduced. However, seasonal systems serving \leq 1,000 people that are not on monthly monitoring by the compliance date of the RTCR may continue with their existing 1989 TCR monitoring frequency afterwards, unless or until any of the conditions for increased monitoring discussed previously in section III.C.1.b.iv of this preamble, *Increased monitoring*, are triggered on or after the compliance date, or as directed by the State. To continue on their existing 1989 TCR monitoring frequency, seasonal systems on less than monthly monitoring at the compliance date of the RTCR must have an approved sample siting plan that designates the time period for monitoring based on site-specific considerations (e.g., during periods of highest demand or highest vulnerability to contamination). The system must collect compliance samples during this time period. Seasonal systems on annual monitoring frequency are required to have a recurring annual site visit by the State (or an annual voluntary Level 2 assessment by a party approved by the State) to remain on annual monitoring.

Only seasonal systems using ground water and serving \leq 1,000 people are eligible for reduced monitoring. To be newly eligible for reduced monitoring after the compliance date, they must meet the following criteria:

- The system must have an approved sample siting plan that designates the time period for monitoring based on site-specific considerations (e.g., during periods of highest demand or highest vulnerability to contamination). The system must collect compliance samples during this time period; and
- To be eligible for reduced quarterly monitoring, the system must also meet all the reduced monitoring criteria discussed in section III.C.1.b.v of this preamble, *Requirements for returning to quarterly monitoring*, and provided in § 141.854(g) of the RTCR.
- To be eligible for reduced annual monitoring, the system must also meet all the reduced monitoring criteria discussed in section III.C.1.b.vi of this preamble, *Requirements for returning to reduced annual monitoring*, and provided in § 141.854(h) of the RTCR.

The State may exempt any seasonal system from some or all of the requirements for seasonal systems (e.g., performing start-up procedures) if the entire distribution system remains pressurized during the entire period that the system is not operating. However, systems that monitor less frequently than monthly must still monitor during the time period designated in their approved sample siting plan.

g. Consecutive systems. EPA did not identify any issues regarding consecutive systems in the RTCR. Consecutive systems must monitor for total coliforms at a frequency based on the population served by the consecutive system and the source water type of the wholesale system. In instances where it is justified to treat two or more distribution systems as a single system for monitoring purposes, 40 CFR 141.29 allows the State to modify the monitoring requirements for the combined distribution system. Any modifications to the monitoring requirements must be approved by EPA. The State may not, however, modify the compliance requirements. The RTCR is not modifying the provisions of 40 CFR 141.29. When conducting assessment and

corrective action under the RTCR, wholesalers and consecutive systems should cooperate as directed by the State and conduct assessment and corrective action based on the location of the positive sample results, the potential pathways of distribution system contamination, and the sanitary defects identified.

2. Key issues raised

a. Sample siting plans. The majority of the comments EPA received supported the proposal that sample siting plans be subject to State review and revision instead of requiring State approval. The advisory committee recommended that States review and revise sample siting plans consistent with current practice and that the State develops and implements a process to ensure the adequacy of sample siting plans. EPA also received comments that requiring State approval of sample siting plans will be an additional burden to the States. Considering these comments and the recommendation of the advisory committee, EPA, therefore, is not changing the requirement regarding State review and revision of the sample siting plan in most instances. There are, however, instances where it is necessary for the State to review and approve elements of the sample siting plan, and other instances where the need for State approval is left to State discretion. For example, seasonal systems on less than monthly monitoring must have an approved sample siting plan that designates the time period for collecting the sample(s) as discussed previously in section III.C.1.f of this preamble, *Seasonal systems*. On the other hand, for systems that want to establish repeat sampling locations other than the within-five-connections-upstream-and-downstream of the total coliform-positive sample, the system must submit the siting plan for review and the State may modify the sampling locations as needed, but State approval is not required by the RTCR, as discussed in section III.D of this preamble, *Repeat Samples*.

EPA received comment that supported the use of dedicated sampling locations. Although not specifically addressed this practice is already in use by some States and systems under the 1989 TCR. As discussed in the proposed RTRC, EPA is specifically allowing the use of dedicated sampling stations for the following reasons:

- To reduce potential contamination of the sampling taps. Utilities will have more control to prevent contamination of the sampling tap by preventing its use by unauthorized persons and allowing no routine use of the tap except for sampling.
- To facilitate access to sampling taps. Currently systems may be constrained by where they sample, e.g., only at public buildings or in certain individual customer's house.
- To improve sampling representation of the distribution system. Allowing dedicated sampling taps in areas where systems have not been able to gain access will facilitate better sampling representation of the distribution system.

b. Ground water NCWSs serving $\leq 1,000$ people. EPA received comments regarding the monitoring requirements for small ground water NCWSs. Many of the commenters agreed with the requirements proposed while some commenters suggested that systems should not be allowed to monitor less than monthly.

The advisory committee recommended that the routine monitoring frequency for ground water NCWSs serving 1,000 or fewer people remain at quarterly monitoring as provided in the 1989 TCR. EPA believes that quarterly monitoring carried out in conjunction with the assessment and corrective action requirements would maintain or improve public health protection without increasing sampling costs over the 1989 TCR requirements. The advisory committee also recognized that current sampling costs are not insignificant for small systems, and wanted to allow reduced monitoring for well-performing systems under the more specific

and rigorous criteria described previously in sections III.C.1.b.iii, *Reduced monitoring*, and III.C.1.c.iii, *Reduced monitoring*, of this preamble. To continue to provide adequate health protection, systems on reduced monitoring must adhere to criteria that ensure that barriers are in place and are effective. Furthermore, systems with problems that may indicate poor system integrity, maintenance, or operations, or systems that fail to monitor, are triggered into more frequent monitoring. This approach leverages the limited resources of small ground water NCWSs and of States, so that well-operated systems can minimize their costs and States can focus their resources on systems needing the greatest attention, such as systems with problems or vulnerabilities.

EPA requested comment in the proposed rule on whether to require NTNCWSs to comply with the CWS requirements (as they are in other rules such as disinfection byproduct (DBP) rules) since NTNCWSs serve the same people over time and include populations that may be at greater risk (e.g., schools, hospitals, daycare centers).

EPA received comments both in agreement and disagreement with this approach. Those who disagreed stated that such requirement would result in disproportionate impact on NTNCWS, since these systems are small systems with limited resources. One commenter said that the 1989 TCR has been in effect for decades now and there have been no adverse health effect impacts by not having NTNCWSs comply with CWS requirements.

Considering the comments EPA received, the Agency is not requiring NTNCWSs to comply with CWS requirements under the RTCR. However, EPA recommends that States consider the population served at NTNCWSs, especially those that serve sensitive subpopulations such as schools, hospitals, and daycare centers, when they decide on an appropriate monitoring

frequency. EPA is aware that some States are already doing so and suggests that other States consider the same.

EPA received comments that the criteria for returning to reduced monitoring are overly strict, including a suggestion that the requirement to have an additional barrier enhancement to return to annual monitoring is too burdensome and costly. Some commenters stated that systems that are triggered into increased monitoring will be unlikely to return to reduced monitoring. Another commenter suggested that a system should be able to return to reduced monitoring sooner than 12 months.

EPA continues to believe that for a system to be able to monitor only once a year, it should be able to demonstrate that it has the ability to continually deliver safe water by ensuring that barriers are in place to protect against contamination. A system that has been triggered into increased monitoring has failed in some way to demonstrate that it has those barriers in place. The requirements to return to reduced monitoring are intended to show that the system has made the long-term commitment and provided the necessary additional barriers to eliminate the vulnerability to contamination that triggered the increased monitoring in the first place. EPA believes that the requirements for returning to reduced monitoring are not impossible to meet but require an appropriate level of effort over at least 12 months to show the commitment and ability to deliver safe water.

EPA received comments regarding monitoring violations as a trigger for increased monitoring and as part of the criteria for returning to reduced monitoring. EPA heard from States with large numbers of NCWSs that including monitoring violations as a trigger for increased monitoring and as part of the criteria for reduced monitoring will make the RTCR difficult to implement in their States. NCWSs, especially TNCWSs, pose unique challenges to

rule compliance as they typically do not have the resources that CWSs have and providing water is not their primary business. Commenters suggested that triggering a NCWS into increased monitoring because of just one or two missed samples is not appropriate and will burden the State with compliance and enforcement tracking. They indicated that this will shift limited State resources away from oversight activities for CWSs that serve large populations to compliance and enforcement activities for NCWSs that serve small populations, resulting in decreases in public health protection. The commenters also concluded that once a system is triggered into increased monitoring, it would not be able to qualify for reduced monitoring because it would not be able to meet the requirements for clean compliance history (e.g., no monitoring violations).

EPA recognizes the burden on States that may result from implementing the increased and reduced monitoring provisions of the RTCR. EPA is therefore providing States the flexibility to not count monitoring violations towards eligibility for remaining on quarterly monitoring or for returning to quarterly monitoring as long as a make-up sample is collected by the end of the next monitoring period. This flexibility only applies to TNCWSs and only for routine samples. The State cannot use this flexibility to qualify a system for annual monitoring. When exercising the flexibility about whether to count a monitoring violation towards eligibility for reduced monitoring, the State may find it appropriate to also consider the system's history of monitoring violations. The TNCWSs would still incur a monitoring violation and must comply with the other associated requirements after such violation (e.g., public notification and reporting).

In the proposed rule, a NCWS on annual monitoring with one RTCR monitoring violation is triggered into monthly monitoring. Some commenters expressed concern that many systems on annual monitoring will be triggered to monthly monitoring because of just one missed sample.

The commenters stated that this was unreasonable considering that these systems typically do not have the resources that CWSs have, such as a certified operator. These systems typically experience frequent staff shortages or turnover that result in missed samples. Having these systems do monthly monitoring would require significant tracking and enforcement activities on the part of the State.

To address this concern, EPA has changed the consequence of having one RTCR monitoring violation for systems on annual monitoring. Instead of having to go to monthly monitoring, the system now moves to quarterly monitoring. EPA also believes that the annual site visit by the State, and the fact that some States conduct and/or pay for the annual monitoring, reduces the likelihood that systems on annual monitoring will miss samples and be triggered to increase to quarterly monitoring, so that PWS and State resource needs are not likely to significantly increase because of this requirement. EPA is not changing the consequence of exceeding the other triggers for increased monitoring; systems that experienced any of the other events in section III.C.1.b.iv of this preamble, *Increased monitoring*, will need to monitor monthly instead of quarterly. Systems can go back to annual monitoring by meeting the criteria for reduced monitoring.

EPA requested comment on whether daily chlorine residual measurements should be one of the criteria for reduced monitoring. EPA received comments that said that it should not be a criterion. Some commenters expressed concern that one missed measurement might be a basis for being bumped to increased monitoring. One commenter suggested giving the State the discretion to either allow or not allow it as a criterion. Section 141.854(h)(2)(iii) of the RTCR specifies that one of the enhancements to water system barriers to contamination is continuous disinfection entering the distribution system and a residual in the distribution system in

accordance with criteria specified by the State. States are given the discretion to decide how they want to implement this criterion based on site-specific considerations. States may want to require daily measurement of chlorine residual to demonstrate continuous disinfection.

One commenter expressed concern that a reduction in the number of additional routine samples (i.e., from five to three) reduces the likelihood of detecting both total coliforms and *E. coli*. The advisory committee recommended that it is appropriate to drop from five to three samples the following month to reduce monitoring costs while still maintaining a substantial likelihood of identifying a problem if a problem persists. EPA and the advisory committee recognized that a reduction in the number of samples taken could also mean a reduction in the number of positive samples found. However, EPA and the advisory committee concluded that the new assessment and corrective action provisions of the RTCR lead to a rule that is more protective of public health and to improvement in water quality despite the reductions in the number of samples taken. The Final RTCR EA occurrence modeling results support this conclusion, as they predict that more *E. coli* MCL violations will be prevented and total coliform and *E. coli*-positive hit rates will decrease when assessment and corrective action occur. See chapter 6 of the Final RTCR EA (USEPA 2012a) for more details.

c. Seasonal systems. EPA received comments that disagreed with the routine monthly monitoring frequency for seasonal systems. The commenters suggested that requiring a start-up procedure is the essential element and having seasonal systems monitor quarterly like all other NCWSs should be adequate. Other commenters agreed with monthly monitoring.

As discussed in section III.A.4 of this preamble, *Seasonal systems*, seasonal systems are more susceptible to contamination due to changes in the conditions of the source water during the period the system is in operation. Such changes include variable contaminant loading due to

increased septic tank or septic field use, the seasonal nature of the demand, and the stress the system may experience. Because of the risk factors, the advisory committee decided that more frequent monitoring is appropriate for these systems, with the possibility of going on reduced monitoring if they meet certain criteria. EPA concurs with the advisory committee assessment and the final rule maintains the proposed routine monthly monitoring frequency, when they are in operation, for seasonal systems.

One commenter said that a regular sampling schedule is more easily achieved and more practical than identifying vulnerable time periods as these periods can vary from year to year. EPA believes that a system that will monitor less frequently than monthly should sample based on site-specific considerations (e.g., during periods of high demand or highest vulnerability of contamination). This increases the probability of detecting a possible contamination; hence, measures can be taken to address the possible contamination before it becomes a public health threat.

One commenter suggested that start-up procedures must include flushing, disinfection, re-flushing to eliminate disinfectant residual, and taking a sample prior to serving water to the public. EPA is not requiring specific practices regarding the start-up procedure. States are given the flexibility to determine what start-up procedures are appropriate for a particular system based on its site-specific considerations and must describe their process for determining start-up procedures in their primacy application. EPA recommends that States require seasonal systems to take a sample as part of the required start-up procedures. Systems must allow sufficient time for completing start-up procedures (including receiving sample results) and notifying the State as required prior to serving water to the public.

D. Repeat Samples

1. Requirements

Under the RTCR, all PWSs must take at least three repeat samples for each routine sample that tested positive for total coliforms. This is a change from the 1989 TCR requirements where systems serving 1,000 or fewer people must collect at least four repeat samples while the rest of the systems must collect three repeat samples.

As discussed in the preamble to the proposed RTCR, EPA believes that sampling again immediately after determining that a sample is positive (i.e., conducting repeat sampling) increases the likelihood of identifying the source and/or nature of the possible contamination. Analyses conducted by EPA indicated that once a total coliform-positive is found, there is a much greater likelihood of finding another total coliform-positive within a short period of time of the initial finding (see page 40939 of the *Federal Register* (FR) notice for the proposed RTCR (USEPA 2010a, 75 FR 40926, July 14, 2010) for more discussion on the analyses done by EPA regarding repeat samples). Repeat sampling (when it is total coliform-positive) can indicate a current pathway for potential external contamination into the distribution system. EPA recommends that States work with PWSs and laboratories to facilitate timely notification through the most expeditious method (e.g., phone, fax, or email) to ensure that repeat samples are taken in a timely manner.

The repeat monitoring requirements of the RTCR are essentially the same as the requirements of the 1989 TCR, except for some new provisions promulgated by the RTCR to provide flexibility to States and PWSs. The following requirements are not changing under the RTCR:

- PWSs must collect the repeat samples within 24-hours of being notified that their routine sample is total coliform-positive.

- The State can extend the 24-hour limit on a case-by-case basis. EPA is providing flexibility to this provision as discussed later in this section.
- The State cannot waive the requirement for a system to collect repeat samples.
- In addition to taking repeat samples, PWSs must test each routine total coliform-positive sample for *E. coli*. They must also test any repeat total coliform-positive sample for *E. coli*. If *E. coli* is present, the system must notify the State the same day it learns of the positive result, or by the end of the next business day if the State office is closed and the State does not have either an after-hours phone line or an alternative notification procedure.
- The State has the discretion to allow the system to forgo *E. coli* testing in cases where the system assumes that the total coliform-positive sample is *E. coli*-positive. If the State allows a system to forgo *E. coli* testing, the system must still notify the State and comply with the *E. coli* MCL requirements specified in § 141.858.
- The system must collect at least one repeat sample from the sampling tap where the original total coliform-positive sample was taken. Unless different locations are specified in its sample siting plan (this is a new provision of the RTCR and is discussed later in this section), the system must also collect at least one repeat sample at a tap within five service connections upstream, and at least one repeat sample at a tap within five service connections downstream of the original sampling site. The State may waive the requirement to collect at least one repeat sample upstream or downstream of the original sampling site if the total coliform-positive sample is at the end of the distribution system, or one service connection away from the end of the distribution system. EPA notes that it is the location of the repeat sample that is waived, not the required number of repeat samples. A PWS still needs to take

the required repeat sample(s) elsewhere in the distribution system if it is unable to do so upstream or downstream of the original sampling site.

- Systems must collect all repeat samples on the same day. The State may allow systems with a single service connection to collect the required set of repeat samples over a three-day period or to collect a larger volume repeat sample(s) in one or more sample containers of any size, as long as the total volume collected is at least 300 milliliters (ml).
- Systems must collect an additional set of repeat samples for each total coliform-positive repeat sample. As with the original set of repeat samples, the system must collect the additional repeat samples within 24 hours of being notified of the positive result, unless the State extends the time limit. The system must repeat this process until either total coliforms are not detected in one complete set of repeat samples or, as the RTCR is adding, the system determines that the coliform treatment technique trigger has been exceeded and notifies the State. After a trigger (see section III.E, of this preamble, *Coliform Treatment Technique*) is reached, the system is required to conduct only one round of repeat monitoring after each total coliform-positive or *E. coli*-positive routine sample. If a trigger is reached as a result of a repeat sample being total coliform- or *E. coli*-positive, no further repeat monitoring related to that sample is necessary.
- A subsequent routine sample, which is within five service connections of the initial routine sample and is collected after an initial routine sample but before the system learns the initial routine sample is total coliform-positive, may count as a repeat sample instead.
- A ground water system with a single well serving 1,000 or fewer people may still use a repeat sample collected from a ground water source to meet both the repeat monitoring requirements of the RTCR and the triggered source monitoring requirements of the GWR

(i.e., a dual purpose sample). Modifications to this provision under the RTCR are discussed later in this section.

As mentioned previously, the RTCR adds some new provisions to the repeat monitoring requirements to provide flexibility to the States and PWSs. One of these changes is the additional flexibility provided to States regarding the waiver or the extension of the 24-hour limit for a PWS to collect repeat samples. States are given the option to describe in their primacy application the criteria they will use to waive or extend the 24-hour limit instead of making the decisions on a case-by-case basis. This is discussed further in section V of this preamble, *State Implementation*.

Another change is the use of alternative monitoring locations. As discussed in section III.C of this preamble, *Monitoring*, the PWS may propose alternative repeat monitoring locations that are expected to better characterize or identify pathways of contamination into the distribution system. Systems may elect to specify either alternative fixed locations or criteria for selecting their repeat sampling locations on a situational basis in a standard operating procedure (SOP), which is part of the sample siting plan. By allowing systems to specify criteria for selecting their repeat sampling locations in their SOP instead of setting fixed repeat sampling locations, systems can provide a more flexible and more protective response. The system can focus the repeat samples at locations that will best verify and determine the extent of potential contamination of the distribution system based on specific situations. For discussion on additional requirements for alternative monitoring locations, see section III.C of this preamble, *Monitoring*.

There are also some modifications to the dual purpose sampling allowed under the GWR and 1989 TCR. Ground water systems required to conduct triggered source monitoring under the GWR must take ground water source samples in addition to the repeat samples required by the

RTCR. However, a ground water system serving 1,000 or fewer people may use a repeat sample collected from a ground water source to meet both the repeat monitoring requirements of the RTCR and the source water monitoring requirements of the GWR (i.e., a dual purpose sample), but only if the State approves the use of a single sample to meet both rule requirements and the use of *E. coli* as a fecal indicator for source water monitoring. If the sample is *E. coli*-positive, the system violates the *E. coli* MCL under the RTCR and must also comply with the GWR requirements following a fecal indicator-positive sample. These provisions are consistent with the GWR.

If a system with a limited number of monitoring locations (such as a system with only one service connection or a campground with only one tap) takes more than one repeat sample at the triggered source water monitoring location, the system may reduce the number of additional source water samples by the number of repeat samples taken at that location that were not *E. coli*-positive. For example, if a system takes two dual purpose samples and one is *E. coli*-positive and the other is *E. coli*-negative, the system has an *E. coli* MCL violation under the RTCR and is required to take four additional source water samples, rather than five, under the GWR (see 40 CFR 141.402(a)(3)). If the system takes more than one of these repeat samples at the triggered source water monitoring location and has more than one repeat sample that is *E. coli*-positive at the triggered source water monitoring location, then the system would have both an *E. coli* MCL violation under the RTCR and a second fecal indicator-positive source sample under the GWR. The system would then need to also comply with the GWR treatment technique requirements under 40 CFR 141.403.

Results of all routine and repeat samples not invalidated by the State must be used to determine whether the coliform treatment technique trigger has been exceeded (see section III.E

of this preamble, *Coliform Treatment Technique*, for a discussion of the coliform treatment technique triggers).

2. Key issues raised

A majority of the commenters supported the change from four to three repeat samples for systems serving 1,000 or fewer people. However, one commenter stated that decreasing the number of repeat samples would also lessen the likelihood of detecting total coliforms and *E. coli*. EPA explained the analysis that EPA has done to support the reduction in the number of repeat samples in the preamble to the proposed RTCR. In that analysis, using the Six-Year Review 2 data (USEPA 2010c), EPA showed that if the number of required repeats were reduced from four to three, there would still be almost as many (approximately 94 percent) situations leading to an assessment being triggered for the system. See section III.A.4 of the preamble to the proposed RTCR, *Repeat Samples*, for a detailed discussion of EPA's analysis on the reduction of the number of repeat samples. Although dropping the required number of repeat samples from four to three means that some fraction of triggered assessments may be missed, the other provisions of the RTCR compensate for that change and, taken as a whole, the provisions of the RTCR provide for greater protection of public health. One such provision includes enhanced consequences for monitoring violations. For example, systems that do not take all of their repeat samples under the RTCR are triggered to conduct a Level 1 assessment. This permits an increase in public health protection over the 1989 TCR because PWSs are required to assess their systems when lack of required monitoring creates a situation where the PWS does not properly know whether it is vulnerable to contamination. Moreover, because of the substantial cost of this potential consequence, systems would be more likely to take all of their

required repeat samples in the first place (see section III.E of this preamble, *Coliform Treatment Technique*, for additional discussion on the coliform treatment technique triggers).

EPA also received comments generally supporting the use of alternative sites for repeat monitoring since they provide more flexibility in determining the locations of the repeat samples, allowing for better protection of public health on a site-specific basis, subject to State review. One commenter disagreed, saying that repeat samples should be near the original positive sample site so that they can provide the necessary information to confirm the original positive sample. A few commenters are against having within-five-connections-upstream-and-downstream locations from the original positive sample as the default locations for repeat monitoring. They suggested that these default locations should be eliminated altogether and that all PWSs be allowed to take the other two repeat samples at alternative locations.

EPA believes that not all systems will use the option of taking repeat samples at alternative locations. Some PWSs, especially small NCWSs, may not avail themselves of this option for reasons of simplicity and lack of resources and expertise. They may elect to stick with the set repeat monitoring locations of five connections upstream and downstream of the original total coliform-positive sample, as it will be less burdensome on them than locating alternative sites and demonstrating that the alternative sites are more effective. Hence, EPA is maintaining within-five-connections-upstream-and-downstream locations as the default repeat sampling locations.

While the prescribed locations may work for some systems, other systems may find them too limiting. Taking repeat samples at the prescribed locations of within five-connections-upstream-and-downstream can be difficult for some systems to implement within the required 24 hours for a repeat sample because of issues such as access to the site. Therefore, EPA is allowing PWSs to

propose alternative repeat monitoring locations, either as fixed locations or as criteria in an SOP, to facilitate the identification of the source and extent of any problem. EPA believes that both the within-five-connections-upstream-and-downstream repeat sampling locations and the locations as identified by an SOP can be used by the operator to better understand the extent and duration of potential pathways of contamination into the distribution system with the appropriate amount of State supervision.

EPA requested comment on whether systems should be required to obtain prior State approval for using repeat monitoring sites other than the within-five-connections-upstream-and-downstream locations of the original routine total coliform-positive site. Most of the commenters were against requiring prior State approval for the use of alternative repeat monitoring locations. They suggested that it is more appropriate to include these sites (or the criteria to choose sites) in the SOP or in the sample siting plan, which is then subject to State review and revision. Some commenters also stated that requiring pre-approval for each individual instance of using alternative sites is not practical.

EPA agrees that obtaining prior State approval to use alternative repeat monitoring locations is not necessary since there is no reduction in monitoring and EPA expects the SOP to be used only by large systems with the technical resources to justify alternative monitoring sites. Although State approval is not required, EPA requires PWSs that are intending to use this option to submit their proposed alternative sampling sites (as part of an SOP or the sample siting plan) to the State. The PWS must be able to demonstrate to the State that the alternative monitoring sites are appropriate to help characterize the extent of the possible contamination. The State is given the discretion to review and revise the alternative monitoring locations consistent with their practice regarding sample siting plans. EPA does not require that the State formally

acknowledge and approve the alternative monitoring locations. The alternative monitoring locations are considered appropriate unless the State disapproves or modifies them, which results in the requirement being self-implementing.

EPA received general support for allowing samples taken at the ground water source to serve both as a triggered source sample under the GWR and as one of the repeat samples under the RTCR (i.e., as dual purpose samples). Some States said that this practice is already being done in their States and therefore should continue under the RTCR. Most commenters supported the provision with the understanding that the practice would be subject to State approval. One commenter, however, disagreed with the provision and thought the PWS would not be collecting a sufficient number of repeat samples to represent the water quality in the distribution system if one of the repeat samples is taken at the source water. Another commenter suggested making the option available for ground water systems of all sizes, as it will help reduce labor and analytical costs, and will provide a clearer picture as to the location and cause of the total coliform-positive sample.

The preamble to the proposed RTCR discussed the drawbacks to allowing dual purpose samples i.e., a reduction in the number of repeats in the distribution system. By requiring State approval of the use of dual purpose sampling, the RTCR ensures that this flexibility will only be allowed where the State has determined it is appropriate. EPA believes that PWSs with limited or no distribution systems are the best candidates for approval since there is little to no chance of contamination from the distribution system except from cross connection. On the other hand, EPA believes that dual purpose samples may not be appropriate for systems with extensive distribution systems because the reduction in monitoring (i.e., one less repeat sample in a

distribution system that extends far from the source water sample site) may not provide public health protection equivalent to taking separate samples.

EPA requested comment on whether the use of dual purpose samples should be allowed by simply including it in the sample siting plan, without prior State approval. As stated earlier, most of the comments supported allowing dual purpose sampling with the understanding that it will be approved by the State. Some commenters, on the other hand, said that it should be allowed without prior State approval. One commenter said that the State may not be able to review and approve the sample siting plan until the next sanitary survey, which maybe as long as five years after the RTCR implementation. One commenter said that States should only be required to say that dual purpose sampling is not allowed for specific systems. Another commenter suggested allowing States to explain their process for approval in their primacy application, rather than each situation being handled on a case-by-case basis, thereby reducing administrative burden.

As discussed earlier, EPA believes that requiring State approval for allowing dual purpose sampling limits the practice only to systems that can avail themselves of it without compromising public health protection. State approval is required because this constitutes a reduction in monitoring (no separate triggered source water samples), relative to requiring separate samples for compliance with the two rules. EPA believes this reduction in monitoring is appropriate only if the State determines that the dual purpose sample provides public health protection equivalent to that provided by separate repeat and source water samples.

As part of the special primacy requirements for the RTCR in § 142.16(q), States adopting the reduced monitoring provisions of the RTCR, including dual purpose sampling, must describe how they will do so in their primacy application package. States must include their approval

process for dual purpose sampling in their application. This gives States the flexibility to determine how and when they want to grant approval, i.e., whether on a case-by-case basis (whenever a total coliform-positive occurs) or on a pre-approved basis (i.e., the system has prior State approval to take a dual purpose sample whenever it is triggered to do source water monitoring).

E. Coliform Treatment Technique

1. Coliform treatment technique triggers

a. Requirements. The non-acute MCL violation for total coliforms under the 1989 TCR is replaced under the RTCR by a coliform treatment technique involving monitoring for total coliforms and assessment and corrective action when triggered. EPA is establishing an assessment process in the RTCR to strengthen public health protection. Under the 1989 TCR, a system is not required to perform an assessment following a monthly/ non-acute MCL violation or an acute MCL violation. Under the RTCR treatment technique framework, the presence of total coliforms is used as an indicator of a potential pathway of contamination into the distribution system. As discussed in section III.B of this preamble, *Rule Construct: MCLG and MCL for E. coli and Coliform Treatment Technique*, the RTCR eliminates the associated MCLG and MCL for total coliforms. The RTCR specifies two levels of treatment technique triggers, Level 1 and Level 2, and their corresponding levels of response. The degree and depth to which a PWS must examine its system and monitoring and operational practices, i.e., the difference between a Level 1 or Level 2 assessment, depends on the degree of potential pathway for contamination. A Level 2 assessment requires a more in-depth and comprehensive review of the PWS compared to a Level 1. A discussion of the levels of assessments is found later in section III.E.2 of this preamble, *Assessment*.

The system has exceeded the trigger immediately once any of the following conditions have been met.

Level 1 treatment technique triggers

- For systems taking 40 or more samples per month, the PWS exceeds 5.0 percent total coliform-positive samples for the month; or
- For systems taking fewer than 40 samples per month, the PWS has two or more total coliform-positive samples in the same month; or
- The PWS fails to take every required repeat sample after any single routine total coliform-positive sample.

The first two treatment technique triggers were the conditions that define a non-acute MCL violation under the 1989 TCR. The third trigger provides incentive for systems to take their repeat samples to ensure that they are assessing the extent of the total coliform contamination; if they do not do so by repeat sampling, they must conduct an assessment instead to ensure there are no pathways to contamination (sanitary defects). Repeat monitoring is critical in identifying the extent, source, and characteristics of fecal contamination in a timely manner. EPA's analysis, as discussed in the preamble to the proposed RTCR (see section III.A.4 of the preamble to the proposed RTCR, *Repeat samples*), shows that the average percentage of repeat samples that are positive is much higher than that of routine samples, demonstrating that when operators are required to take a second look at their systems following the positive routine sample, they find, on average, a higher rate of coliform presence than during routine sampling. In other words, the high repeat total coliform positive rate indicates the persistence of total coliforms at such locations in the distribution system. Since under the RTCR there is no additional routine monitoring for systems that monitor at least monthly and the number of additional routine

monitoring and repeat monitoring samples for the smallest systems that are not on monthly monitoring is decreased, the need to conduct repeat monitoring is more crucial than ever in providing immediate and useful information needed to protect public health.

Level 2 treatment technique triggers:

- The PWS has an *E. coli* MCL violation (see section III.F of this preamble, *Violations*, for a description of what constitutes an *E. coli* MCL violation); or
- The PWS has a second Level 1 treatment technique trigger within a rolling 12-month period, unless the initial Level 1 treatment technique trigger was based on exceeding the allowable number of total coliform-positive samples, the State has determined a likely reason for the total coliform-positive samples that caused the initial Level 1 treatment technique trigger, and the State establishes that the system has fully corrected the problem; or
- For PWSs with approved reduced annual monitoring, the system has a Level 1 treatment technique trigger in two consecutive years.

b. Key issues raised. EPA received comments that disagreed with the inclusion of the third Level 1 treatment technique trigger, i.e., failing to take every required repeat sample after any single routine total coliform-positive sample triggers a Level 1 assessment. Some of the commenters suggested that this does not pose a public health concern and should remain a monitoring violation because if a system does not conduct the required repeat monitoring, then it is doubtful that it will conduct the assessment. One commenter was concerned that a system might opt to conduct the assessment instead of taking the repeat samples and just indicate in the assessment form that no sanitary defect was found or the cause of the total coliform-positive sample could not be identified. The system then avoids the possibility of the repeat samples

being total coliform- or *E. coli*-positive. They commented that since the Level 1 assessment is done by the system, doing the assessment will also be cheaper than taking the repeat samples.

EPA disagrees that the PWS will avoid taking repeat samples because of economic reasons. EPA's analysis indicates that a Level 1 assessment costs about four times as much as taking three repeat samples (see Exhibits 3-12 and 4-7 of the *Technology and Cost Document for the Final Revised Total Coliform Rule* (USEPA 2012b)). States also must review the assessment form submitted by the PWS. If the assessment and/or corrective action is/are not acceptable to the State, the State can require the PWS to redo the assessment and submit a revised assessment form. EPA also expects that in situations where the cause of the total coliform- or *E. coli*-positive result cannot be identified, the PWS will arrive at this conclusion only after due diligence on its part (i.e., the system adheres to proper procedures and standards set by the State in conducting the assessment). The State may require the PWS to provide supporting documentation and analyses to back-up its finding. Because of the cost and the effort involved in conducting a Level 1 assessment, EPA expects that systems will want to ensure that assessments are conducted only when potential problems may exist rather than for failure to take repeat samples.

One commenter suggested that EPA clarify that collecting samples outside the 24-hour required time is not a Level 1 trigger as there are instances when the repeat samples cannot be collected within 24 hours of the routine total coliform-positive sample. EPA notes that there is a provision in the RTCR, § 141.858(a)(1), that allows the State to extend the 24-hour limit on a case-by-case basis if the system has a logistical problem in collecting the repeat samples within 24 hours that is beyond its control. In such cases when the State allows the system to collect the repeat samples beyond the 24 hours, the system does not trigger a Level 1 assessment.

One commenter suggested that EPA include an additional provision that an assessment need not be triggered if the total coliform-positive occurred when there are representative levels of disinfectant residual in the distribution system, stating that historical total coliform-positive results occurred with normal levels of chlorine residuals in the distribution system and did not cause any waterborne disease. EPA disagrees that there is no public health risk in this situation. The fact that total coliforms can be detected even in the presence of a disinfectant residual is an indication that there might be a bigger, hidden problem that needs further investigation. An assessment is warranted to determine if there exists a potential pathway of contamination into the distribution system and corrective action is warranted if a sanitary defect is identified.

EPA received comments to eliminate the Level 2 treatment technique trigger where a second Level 1 assessment is triggered within a rolling 12-month period, or for systems on annual monitoring, where two Level 1 assessments in two consecutive years trigger a Level 2 assessment. Some of the commenters thought that many small systems will be triggered to conduct a Level 2 assessment multiple times. EPA believes that although the conditions (i.e., a second Level 1 trigger) that lead to the Level 2 trigger do not necessarily pose an immediate acute public health threat, it may still pose a potential serious health impact because of the persistence of the contamination and the failure of the system to address it. EPA believes that a Level 2 assessment is warranted in this case because a more in-depth examination of the system is needed to determine the cause of the persistent occurrences of total coliforms. EPA also notes that, ideally, a well-performed Level 1 assessment and appropriate corrective action will prevent most systems from developing conditions that lead to a Level 2 assessment.

2. Assessment

a. Requirements. There are two levels of assessment based on the associated treatment technique trigger: Level 1 assessment for a Level 1 treatment technique trigger and Level 2 assessment for a Level 2 treatment technique trigger. At a minimum, both Level 1 and 2 assessments must include review and identification of the following elements:

- Atypical events that may affect distributed water quality or indicate that distributed water quality was impaired;
- Changes in distribution system maintenance and operation that may affect distributed water quality, including water storage;
- Source and treatment considerations that bear on distributed water quality, where appropriate;
- Existing water quality monitoring data; and
- Inadequacies in sample sites, sampling protocol, and sample processing.

The system must conduct the assessment consistent with any State directives that tailor specific assessment elements with respect to the size and type of the system and the size, type, and characteristics of the distribution system. The PWS must complete the assessment as soon as practical after the PWS learns it has exceeded a treatment technique trigger. Failure to conduct a triggered assessment is a treatment technique violation. See section III.F.1.b of this preamble, *Coliform treatment technique violation*.

Level 1 assessment

A Level 1 assessment must be conducted when a PWS exceeds one or more of the Level 1 treatment technique triggers specified previously. Under the rule, this self-assessment consists of a basic examination of the source water, treatment, distribution system and relevant operational practices. The PWS should look at conditions that could have occurred prior to and caused the

total coliform-positive sample. Example conditions include treatment process interruptions, loss of pressure, maintenance and operation activities, recent operational changes, etc. In addition, the PWS should check the conditions of the following elements: sample sites, distribution system, storage tanks, source water, etc.

Level 2 assessment

A Level 2 assessment must be conducted when a PWS exceeds one or more of the Level 2 treatment technique triggers specified previously. It is a more comprehensive examination of the system and its monitoring and operational practices than the Level 1 assessment. The level of effort and resources committed to undertaking a Level 2 assessment is commensurate with the more comprehensive investigation and review of available information, and engages additional parties and expertise relative to the Level 1 assessment. Level 2 assessments must be conducted by a party approved by the State: the State itself, a third party, or the PWS where the system has staff or management with the required certification or qualifications specified by the State. If the PWS or a third party conducts the Level 2 assessment, the PWS or third party must follow the State requirements for conducting the Level 2 assessment. The PWS must also comply with any expedited actions or additional actions required by the State in the case of an *E. coli* MCL violation.

Assessment forms

The PWS must submit the completed assessment form for either a Level 1 or Level 2 assessment to the State for review within 30 days after the PWS learns that it has exceeded the trigger. Failure to submit the completed assessment form after the PWS properly conducts the assessment is a reporting violation (see section III.F.1.d of this preamble, *Reporting violation*). If the State determines that the assessment is insufficient, the State will consult with the PWS. If

the State requires revisions after consultation, the PWS must submit a revised assessment to the State on an agreed-upon schedule not to exceed 30 days from the date of the initial consultation.

The completed assessment form must include assessments conducted, all sanitary defects found (or a statement that no sanitary defects were identified), corrective actions completed, and a proposed timetable for any corrective actions not already completed. Upon completion and submission of the assessment form by the PWS to the State, the State must determine if the system has identified the likely cause(s) for the Level 1 or Level 2 treatment technique trigger and, if so, establish that the system has corrected the problem(s). Whether or not the system has identified any sanitary defects or a likely cause for the trigger, the State may determine whether or not the assessment is sufficient, and if it is not, the State must discuss its concerns with the system. The State may require revisions to the assessment after the consultation.

b. Key issues raised. The RTCR requires assessments to identify whether potential pathways of contamination into the distribution system exist after monitoring results indicate the system has exceeded a trigger. However, some commenters disagreed that requiring assessments will result in better public health protection. For one, they stated that assessments are already occurring under the 1989 TCR; hence, there is no need to formally require them. Second, assessments conducted by small systems will not likely be adequate as these systems usually do not have the resources and the capability to conduct a proper assessment. The States will then have to perform the assessments themselves (even the Level 1 assessments), thus adding to State burden. Third, assessments will reduce follow-up sampling and will allow a PWS to “guess assess” the cause of the positive sample.

EPA agrees that there already is some level of assessment and corrective action being performed voluntarily by proactive systems, and accounted for this fact in the economic analyses

for the final RTCR (see chapter 7.4.5 of the RTCR EA (USEPA 2012a), *Assessments*).

However, not all systems are proactive in addressing the probable cause(s) of the positive samples. Under the 1989 TCR, when a system has an MCL violation and any subsequent sampling did not detect total coliforms, the problem may persist despite the subsequent negative samples due to the intermittent nature of microbial contamination and may remain unaddressed. By requiring PWSs to assess their systems when they are triggered to do so, the RTCR aims to build and strengthen the capability of PWSs in ensuring that their systems maintain their integrity and that barriers are in place and are effective. These actions will better protect public health than the additional monitoring with no assessment and corrective action that is allowed under the 1989 TCR.

EPA acknowledges that small systems, especially small NCWSs may not have the knowledge and the resources that other systems, like CWSs, have. However, most small NCWSs are simple systems that often consist of just the source water and a limited distribution system. EPA anticipates then that the level of effort and expertise needed to conduct a Level 1 assessment at these systems will not be considerable. At a minimum, the Level 1 assessment should be conducted or managed by a responsible party of the PWS. While EPA does not expect the Level 1 assessor to be an expert in the requirements of SDWA, the assessor should be someone familiar enough with the system to answer the questions in the Level 1 assessment form or to gather correct information from others who work for the system.

To help in the implementation of the assessment, a PWS may conduct a Level 1 assessment while it consults with the State by phone. This is in lieu of having the State physically perform the assessment when the PWS needs assistance. Generally, the PWS would still need to fill-out the assessment form and submit it to the State. The State would still need to review the form but

the process will not take as much effort as previously anticipated since the State would already be familiar with that particular assessment. It is also permissible that the State fill out the form while the PWS consults with the State by phone when doing the assessment. The State may also want to set up alternative methods for the PWS to submit the assessment form, such as via an online submission or email. The State should document its process in the primacy application.

EPA disagrees that the assessment requirements will reduce follow-up sampling. PWSs are still required to take repeat samples following a routine total coliform-positive sample. PWSs on quarterly or annual monitoring must conduct additional routine monitoring the month following the total coliform-positive sample. In addition, nothing in the treatment technique requirements precludes a PWS from taking additional compliance samples or special purpose samples such as those taken to determine whether disinfection practices are sufficient following pipe replacement or repairs (see § 141.853(b) of the RTCR).

EPA disagrees that PWSs conducting the assessment will “guess assess” the cause of the positive samples. Conducting an assessment is a methodical process that requires a PWS to evaluate the different elements of its operation and distribution system (§ 141.859(b)(2) of the RTCR specifies the minimum elements that an assessment must have, keeping in mind that some of the elements may not be applicable to some PWSs like small NCWSs). The RTCR requires that an assessment form be completed. The assessment form should help and guide the PWS in conducting the assessment by laying out the different elements the PWS must look into. EPA provides examples of assessment forms that States and PWSs can use to help them in conducting the assessment (these examples are given in Appendix X of the AIP (USEPA 2008c) and in Appendix A of the *Proposed Revised Total Coliform Rule Assessments and Corrective Actions Guidance Manual – Draft* (USEPA 2010d)). EPA also acknowledges that an assessment will not

always identify sanitary defects or find a reason or cause for the presence of total coliforms and/or *E. coli*. In such cases, the PWS must document that fact in the completed assessment form. This, however, is not “guess assessing” as EPA expects that only PWSs that adhere to proper procedures and standards set by the State are eligible to arrive at this determination. It is then the responsibility of the State to determine if the assessment was acceptable.

Some commenters suggested that for systems with limited distribution systems that have a first Level 1 trigger, the Level 1 assessment should be delayed and the focus of the evaluation should be on the source water, and the Level 1 assessment should only be conducted if there is another Level 1 trigger.

The system may conduct an integrated assessment that meets the requirements of all applicable rules, such as the GWR and the RTCR, as long as the assessment is consistent with any State directives that tailor specific assessment elements with respect to the size and type of the system and the size, type, and characteristics of the distribution system, as required under § 141.859(b)(2) of the RTCR. EPA further notes that source water issues are one of the elements that need to be considered in a Level 1 (or 2) assessment where they may be a contributing factor to a coliform exceedance or other trigger. EPA expects that assessments at PWSs with limited or no distribution systems will be relatively simple assessments and can be tailored to meet applicable requirements of both the GWR and the RTCR. EPA will address this in the revised *Revised Total Coliform Rule Assessment and Corrective Actions Guidance Manual* that is being developed.

EPA received comments both in support and against having two levels of assessment. The commenters in the second category concluded that both levels of assessment would involve the same effort. There were comments to eliminate the Level 1 assessment and emphasize the Level

2 assessment, as the Level 1 assessment will not lead to any meaningful evaluation and will only take up the State's resources. EPA disagrees that there is no need for two levels of assessment. The RTCR requires two levels of assessment to recognize that a higher level of effort to diagnose a problem should be applied to situations of greater potential public health concern such as repeated Level 1 triggers or an *E. coli* MCL violation. A Level 1 assessment is not as comprehensive as Level 2 assessment. This however, does not negate the importance of a Level 1 assessment. Triggers that lead to a Level 1 assessment may indicate the possibility of a breach of the barriers in place. It is important that PWSs ensure that these barriers remain intact by performing the assessment.

EPA received comments that the qualifications of assessors are not clear in the rule. The commenters suggested including the qualifications in the rule or referencing the qualifications described in the *Proposed RTCR Assessment and Corrective Actions Guidance Manual – Draft* (USEPA 2010d). Some commenters concluded that the Level 2 assessment will require a whole new certification program for assessors. Others concluded that the States will end up doing the Level 2 assessment because of what is expected and required of a Level 2 assessment. On the other hand, one commenter suggested that a system operator should be certified to perform an assessment of their own system. Another suggested that States be allowed to set mechanisms in place to ensure that a Level 2 assessment is performed more comprehensively than a Level 1 assessment.

EPA does not require that a separate certification program be established to determine who can perform a Level 2 assessment. Instead of being prescriptive on who can conduct a Level 2 assessment, EPA is allowing the State to determine its criteria and process for approval of Level 2 assessors and to determine who is appropriate to conduct the assessment given the State's

knowledge of the complexity of the system and the knowledge and policies of the State.

Although the rule allows that certified operators may perform a Level 2 assessment if approved by the State, EPA recommends that States consider whether having the assessment done by someone from outside the system can provide a fresh perspective. Qualified certified operators can be allowed to conduct assessments at other systems.

EPA requested comments on how to ensure that a Level 2 assessment is more comprehensive than a Level 1 assessment (e.g., by possibly including asset management and capacity development). EPA asked in the proposed rule whether EPA should provide more detail in guidance or rule language, on the elements and differences between a Level 1 and Level 2 assessment. A majority of the commenters were against the inclusion of asset management and capacity development in the Level 2 assessment. EPA received comments stating that the proposed rule language regarding the two levels of assessment was adequate and that additional discussion about the differences between the two should instead be addressed in guidance. One commenter, on the other hand, said that there was no difference in the scope between the two assessments based on the way the proposed rule language was written.

EPA defined in § 141.2 both a Level 1 assessment and a Level 2 assessment to provide a better distinction between the two levels of assessment and facilitate the implementation of the RTCR. See section III.A.1 of this preamble, *Assessment*, for the definitions of a Level 1 and Level 2 assessment. EPA is also requiring States to describe in their primacy application how they will ensure that a Level 2 assessment is more comprehensive than a Level 1 assessment; thus, giving the States more flexibility in implementing the rule. EPA released the *Proposed Revised Total Coliform Rule Assessments and Corrective Actions Guidance Manual – Draft* (USEPA 2010d) in August 2010 to help stakeholders understand the difference between the two

levels of assessment. EPA will revise this guidance manual based on the comments received and release it soon after the final RTCR is published in the *Federal Register*.

EPA received comments to allow the extension of the assessment period beyond 30 days. A commenter suggested that intermediate deadlines for a Level 2 assessment triggered by the presence of *E. coli* be included because of the acute nature of the threat.

EPA expects that the PWS will conduct an assessment as soon as practical after the PWS receives notice or becomes aware that the system has exceeded a trigger. EPA imposes a 30-day limit because the possible occurrence of contamination, as indicated by the conditions that trigger the assessment, must be addressed immediately. The system has 30 days from the time it learns of exceeding the trigger to conduct the assessment and complete the corrective action. EPA believes that the 30-day period is sufficient time for problem identification and potential remediation of the problem in conjunction with the follow-up assessment in most cases. The system can work out a schedule with the State to complete the corrective action if more time is needed. It is very important, however, that the assessment is conducted as soon as possible within those 30 days. In the case of an *E. coli* MCL violation, the system must comply with any expedited actions or additional actions required by the State (see § 141.859(b)(4) of the RTCR). EPA also encourages PWSs to submit their completed assessment forms as soon as possible and not wait until the end of the 30-days to do so.

3. Corrective action

a. Requirements. Under the RTCR, PWSs are required to correct sanitary defects found through either a Level 1 or Level 2 assessment. Systems should ideally be able to correct any sanitary defects found in the assessment within 30 days and report that correction on the assessment form. This is especially important when *E. coli* has been detected in samples

collected from the distribution system, indicating that a potential health hazard exists. However, EPA recognizes that correcting sanitary defects within 30 days may not always be possible due to the extent and cost of the corrective action, and that some systems therefore may not be able to fix sanitary defects before submitting the completed assessment form within the 30-day interval. When the correction of sanitary defects is not completed by the time the PWS submits the completed assessment form to the State, EPA encourages the State and PWS to work together to determine the appropriate schedule for corrective actions (which may include additional or more detailed assessment or engineering studies) to be completed as soon as possible. The schedule, which is approved by the State, must include when the corrective action will be completed and any necessary milestones and temporary public health protection measures. The PWS must comply with this schedule and notify the State when each scheduled corrective action is completed.

At any time during the assessment or corrective action phase, either the PWS or the State may request a consultation with the other entity to discuss and determine the appropriate actions to be taken. The system may consult with the State on all relevant steps that the system is considering to complete the corrective action, including the method of accomplishment, an appropriate timeframe, and other relevant information. EPA is not requiring this to be a mandatory consultation to provide ease of implementation for States. In many cases, consultation may not be necessary because the type of corrective action for the sanitary defect will be clear and can be implemented right away (e.g., replacement of a missing screen).

b. Key issues raised. EPA received comments that not all sanitary defects should have to be corrected unless it can be determined the defect directly correlates to the trigger or if the defect is otherwise regulated. Similarly, commenters suggested that EPA clarify that any requirement to

correct sanitary defects found during the assessment be limited only to issues that are within the system's control. In contrast, one commenter encouraged EPA to provide authority to States to require broader corrective actions beyond fixing specific sanitary defects (e.g., requiring development and implementation of a storage tank inspection and maintenance plan).

EPA acknowledges that it may or may not be possible to conclusively link the total coliform-*E. coli*-positive sample to a given sanitary defect due to the complexity of the distribution system configuration and transport of contaminants throughout the system. That being the case, the PWS must still correct all sanitary defects found through the assessment even if the defect cannot be proven to be the likely cause of the positive sample, to prevent the defect from providing a pathway for future contamination. The RTCR takes a more preventive approach to protect public health by requiring that systems perform an assessment of their system when their monitoring results indicate a potential pathway of contamination into the distribution system, or a breach in the barriers that are in place, and correct all identified sanitary defects, regardless of whether the defect is directly related to the positive sample or not. This is because EPA believes that correcting only sanitary defects that are correlated to the positive sample is not sufficiently protective of public health. Uncorrected sanitary defects may provide a pathway for future incidences of contamination.

The RTCR requires that sanitary defects be corrected but does not mandate how the defects are to be corrected. States and PWSs may have other authorities under local ordinances and State laws that they may use to address the problem. For example, in cases where the location of the sanitary defect is outside the normal control of the PWS (e.g., cross connection occurring on private property), community water systems that are part of the local government may have some authority to address the problem under the public health code if the issue is affecting the water in

the distribution system (AWWA 2010) or through other local ordinances such as plumbing codes. EPA encourages States and PWSs to work together to determine the best course of action when correcting sanitary defects.

Some commenters said that it is unclear how a water utility should demonstrate that it has corrected a sanitary defect and how the primacy agency would take enforcement action on any defects identified by the system. One commenter suggested that EPA clarify whether a sanitary defect would be considered corrected if subsequent samples are total coliform-negative. EPA notes that because of the intermittent nature of microbial contamination, it may not be adequate to just rely on follow-up samples to verify that the problem has been corrected or has gone away. Depending on the nature of the sanitary defect, States may require additional measures to ensure that the integrity of the distribution system has been restored (e.g., pressure monitoring, follow-up inspection of tanks, etc.). States have discretion on how to determine that defects have been corrected (e.g., site visits, sanitary surveys, etc.). Failure to correct identified sanitary defects is a treatment technique violation and States are expected to use their legal authority to take enforcement action to return the system to compliance.

F. Violations

1. Requirements

EPA is establishing the definition of the following violations – MCL violation, treatment technique violation, monitoring violation, and reporting violation – consistent with the proposed RTCR. Each type of violation requires public notice, the level of which depends on the severity of the violation (see section III.G of this preamble, *Providing Notification and Information to the Public*, for information on public notification), and may trigger a system on reduced monitoring to increase its monitoring frequency (see section III.C of this preamble, *Monitoring*, for

information on monitoring frequency). In addition to these violations, systems are required to comply with all the requirements of the RTCR, e.g., to use an approved analytic method to test for total coliforms and *E. coli*, to monitor according to a sample siting plan, etc. EPA also would like to clarify that exceeding a trigger and being required to conduct an assessment is not a violation by itself; as described later in this section, a violation occurs when a system exceeds the trigger but does not complete the required assessment and corrective action in response.

a. E. coli MCL violation. A system incurs an *E. coli* MCL violation if any of the following occurs:

- A routine sample is total coliform-positive and one of its associated repeat samples is *E. coli*-positive.
- A routine sample is *E. coli*-positive and one of its associated repeat samples is total coliform-positive.
- A system fails to take all required repeat samples following a routine sample that is positive for *E. coli*.
- A system fails to test for *E. coli* when any repeat sample tests positive for total coliforms.

b. Coliform treatment technique violation. A system incurs a coliform treatment technique violation when any of the following occurs:

- A system fails to conduct a required assessment within 30 days of notification of the system exceeding the trigger (see section III.E of this preamble, *Coliform Treatment Technique*, for conditions under which monitoring results trigger a required assessment).
- A system fails to correct any sanitary defect found through either a Level 1 or 2 assessment within 30 days (see also section III.E of this preamble, *Coliform Treatment Technique*) or in accordance with State-derived schedule.

- A seasonal system fails to complete a State-approved start-up procedure prior to serving water to the public. This is further discussed later on in the *Key issues raised* part of this section.

There is no treatment technique violation associated solely with a system exceeding one or more action triggers (Level 1 or Level 2 triggers).

c. Monitoring violation. A system incurs a monitoring violation when any of the following occurs:

- A system fails to take every required routine or additional routine sample in a compliance period.
- A system fails to test for *E. coli* following a routine sample that is total coliform-positive.

d. Reporting violation. A system incurs a reporting violation when any of the following occurs :

- A system fails to timely submit a monitoring report or a correctly completed assessment form after it properly monitors or conducts an assessment by the required deadlines. The PWS is responsible for reporting this information to the State regardless of any arrangement with a laboratory.
- A system fails to timely notify the State following an *E. coli*-positive sample. See section III.H.1.a of this preamble, *Reporting*, for reporting requirements in the case of an *E. coli*-positive sample.
- A seasonal system fails to submit certification of completion of State-approved start-up procedure. This is further discussed in the *Key issues raised* part of this section.

2. Key issues raised

EPA received comments that supported the proposed definition of the violations. Others offered suggestions to ease implementation burden. For example, one commenter recommended that only one violation be generated for each compliance situation (i.e., if an MCL violation is determined, then neither treatment technique, nor monitoring, nor reporting violation can be generated; if a treatment technique violation is determined, then neither monitoring nor reporting violation can be generated). However, EPA believes that it is important to track each of these situations individually so that the State can be aware of the system's progress resolving situations and complying with all rule requirements. Each situation is also accompanied by public notification requirements so that consumers can be aware of problems at the water system and the progress and efforts to correct them. EPA believes it is important to continue to notify the public of each situation.

Some commenters were uncertain about when failure to take all repeat samples triggers the associated Tier 1 PN (i.e., when the 24-hour clock starts). Some questioned how the State will know when the failure to collect these repeats has occurred in such a way to assure timely Tier 1 PN when the sample results do not need to be reported until the 10th day of the month following the month in which the samples were collected. EPA believes that State programs have been designed to address timely response to follow-up requirements such as the need to take repeat samples, through education, compliance assistance, and tracking and enforcement programs. The time limit is established to assure that systems act promptly to investigate positive samples. Some States require direct electronic reporting of results, which provides for more timely notification, and EPA encourages such practice. In the situations where it is not possible for the system to take the repeat samples within 24 hours, States have the discretion to waive the requirement (see section III.D of this preamble, *Repeat Samples*).

Other commenters suggested adding to the list of violations. EPA received comment that there should be a violation when a seasonal system fails to perform the start-up procedure. EPA agrees and is designating such failure as a treatment technique violation. EPA is also requiring seasonal systems to certify that they have completed the start-up procedure and submit this certification to the State. Failure to do so is a reporting violation. EPA believes that performing start-up procedures is very important to mitigate the possible risks resulting from the seasonal system being shutdown, depressurized, or drained. Designating such failure as a violation will compel seasonal systems to make sure that they take the necessary steps to mitigate public health risks before serving water to the public.

Other commenters, on the other hand, suggested deleting the MCL violation resulting from failure to take all required repeat samples following a routine *E. coli*-positive sample. One commenter suggested that instead of an MCL violation, this should be considered a sanitary defect that requires corrective action. EPA considers *E. coli* as an indicator of a potential pathway of fecal contamination that should be taken seriously. A system needs to follow up with repeat samples to characterize the extent and source of such contamination. Failure to take the required repeat samples following an initial *E. coli*-positive sample is not protective of public health and is a serious violation. Making such failure an *E. coli* violation prevents a system from incurring only a monitoring violation when there is an indication of fecal contamination.

Some commenters do not agree with the treatment technique violation because they do not agree that the treatment technique requirements of the RTCR are appropriate. For a discussion on the treatment technique, see section III.E of this preamble, *Coliform Treatment Technique*. One commenter asked for clarification on whether failure to submit the assessment form within 30 days is a treatment technique violation. As stated previously, this is a reporting violation, not

a treatment technique violation, if the assessment has in fact been completed and the only failure was in submitting the required form. A treatment technique violation occurs when a potential pathway of contamination into the distribution system is unexplored and/or uncorrected. A system that neglects to perform the prescribed assessment or corrective action within schedule is in violation of the treatment technique requirement.

Commenters also supported EPA's proposal of separating the combined monitoring and reporting violation under the 1989 TCR into two separate violations. One commenter noted that it has been difficult to determine the significance of a violation when two types of violations – monitoring and reporting – are captured and reported under only one heading. It is, therefore, difficult to develop performance measures and ensure data quality when the two violations are combined.

G. Providing Notification and Information to the Public

1. Requirements

EPA is promulgating changes to the public notification (PN) requirements contained in 40 CFR part 141 subpart Q to correspond to the violation provisions of the RTCR (see section III.F of this preamble, *Violations*). EPA is requiring a Tier 1 PN for an *E. coli* MCL violation, Tier 2 PN for a treatment technique violation for failure to conduct assessments or corrective actions, and a Tier 3 PN for a monitoring violation or a reporting violation.

Tier 1 PN is required for NPDWR violations and situations with significant potential to have serious adverse effects on human health as a result of short-term exposure, such as could occur with exposure to fecal pathogens. Tier 1 PN is required as soon as possible but no later than 24 hours after the system learns of the violation. An *E. coli* MCL violation indicates possible exposure to pathogens in drinking water that can possibly result in serious, acute health effects,

such as diarrhea, cramps, nausea, headaches, or other symptoms and possible greater health risks for infants, young children, the elderly, and people with severely compromised immune systems.

In the 1989 TCR, if a system has an acute MCL violation, which is based on the presence of fecal coliforms or *E. coli*, or the system's failure to test for fecal coliforms or *E. coli* following a total coliform-positive repeat sample, the system is required to publish Tier 1 PN. Under the RTCR, a system is required to publish Tier 1 PN when it has an *E. coli* MCL violation. (See section III.F of this preamble, *Violations*, for a discussion of MCL violations.) In addition, the system will continue to be required to notify the State after learning of an *E. coli*-positive sample, as required under the 1989 TCR. As mentioned earlier in section III.B of this preamble, *Rule Construct: MCLG and MCL for E. coli and Coliform Treatment Technique*, EPA is eliminating the MCL for fecal coliforms. Under the RTCR, the standard health effects language, which is required to be included in all public notification actions, is modified to delete the reference to the fecal coliform MCL and fecal coliforms. The language for a non-acute violation under the 1989 TCR is modified to apply to a violation of the assessments and corrective action requirements of the coliform treatment technique.

Tier 2 PN is required for all NPDWR violations and situations with potential to have serious adverse effects on human health not requiring Tier 1 PN. The system must provide public notice as soon as practical, but no later than 30 days after the system learns of the violation. A treatment technique violation under the RTCR meets these criteria because it is an indication that the public water system failed to protect public health when the system failed to conduct an assessment or complete corrective action following identification of sanitary defects. Sanitary defects indicate that a pathway may exist in the distribution system that has potential to cause public health concern.

In the 1989 TCR, a system is required to publish a Tier 2 PN when the system has a non-acute MCL violation, which is based on total coliform presence. Under the RTCR, a system is required to publish a Tier 2 PN if the system violates the coliform treatment technique requirements. Also, EPA is modifying the standard health effects language for coliform to emphasize the assessment and corrective action requirements of the RTCR.

Tier 3 PN is required for all other NPDWR violations and situations not included in Tier 1 or Tier 2. The existing Tier 3 PN requires a system to provide public notice no later than one year after the system learns of the violation or situation or begins operating under a variance or exemption. Monitoring and reporting violations have historically been designated as Tier 3 PN unless an immediate public health concern has been identified (e.g., failure to monitor for *E. coli* after a total coliform-positive sample requires a Tier 1 notification.) Where no such immediate public health concern has been identified, EPA believes that a public notice given at least annually for monitoring and reporting violations fulfills the public's right-to-know about these violations.

In the 1989 TCR, a system is required to publish a Tier 3 PN when the system has a monitoring and reporting violation. In the RTCR, monitoring violations are considered distinct from reporting violations. Both types of violations require Tier 3 PN.

Consumer confidence report (CCR) requirements are also modified. Health effects language for the CCR for total coliforms and *E. coli*, which is identical to the health effects language required for PN, is updated in the same way as described for PN. In addition, the RTCR removes the CCR requirements for the inclusion of total numbers of positive samples, or highest monthly percentage of positive samples for total coliforms as well as total number of positive samples for fecal coliforms. These provisions are replaced by requirements to include the

number of Level 1 and Level 2 assessments required and completed, the number of corrective actions required and completed, and the total number of positive samples for *E. coli*. A system that fails to complete all the required assessments or correct all identified sanitary defects has a treatment technique violation and must identify it in the CCR as: (1) failure to conduct all of the required assessment(s); and/or (2) failure to correct all identified sanitary defects. A system that has an MCL violation must also include the condition that resulted in the MCL violation (see section III.B.1 of this preamble, *MCLG and MCL*, and § 141.860(a) of the RTCR). Unchanged and consistent with the provisions under the 1989 TCR, a CWS may provide Tier 3 PN using the annual CCR.

CCR requirements are updated to reflect the advisory committee's recommendations that total coliforms be used as an indicator to start an evaluation process that, where necessary, will require the PWS to correct sanitary defects. EPA believes it is most appropriate to inform the public about actions taken, in the form of assessments and corrective actions, since failure to conduct these activities lead to treatment technique violations under the RTCR. Because the RTCR no longer includes the total coliform MCL but now includes a trigger, EPA believes that systems no longer need to report the number of total coliform-positive samples via the CCR, since that could cause confusion or inappropriate changes in behavior among consumers. In addition, the CCR requirements will also reflect the removal of fecal coliform.

2. Key issues raised

In general, EPA received comments in support of the PN requirements of the RTCR. The commenters stated that the changes are consistent with the intent and recommendations of the TCRDSAC. However, there were a few commenters who disagreed on certain aspects of the requirements. These comments are discussed in detail in the following paragraphs.

EPA requested comment on whether the elimination of the PN associated with the presence of total coliforms (i.e., the Tier 2 PN associated with the non-acute MCL violation under the 1989 TCR) will result in a loss of information to consumers. Although the majority of the commenters said that it would not result in a loss of information, some commenters said that it would. One commenter said that the PN associated with the presence of total coliforms has been an effective tool to motivate PWSs to take corrective actions; to eliminate such PN and replace it with a PN associated with treatment technique violations is not “equal to or better” public health protection. One commenter believed that if the non-acute PN requirement is eliminated, then NCWSs would not have the tool to communicate to the public the possible health risk as these PWSs are not required to send out a CCR.

As EPA discussed in section III.B of this preamble, *Rule Construct: MCLG and MCL for E. coli and Coliform Treatment Technique*, the presence of total coliforms is not, by itself, a public health threat. EPA agrees with comments received that suggest that the Tier 2 PN for a non-acute MCL violation under the 1989 TCR is sometimes unnecessarily alarming as it attributes greater public health significance to the presence of total coliforms than is warranted. EPA believes the removal of the Tier 2 PN for a non-acute MCL violation will help prevent public confusion.

EPA received comments that under the 1989 TCR some States require a Tier 1 PN when a NCWS has a non-acute MCL violation. EPA would like to note that the 1989 TCR requires a Tier 2 PN for a non-acute MCL violation, not a Tier 1 PN. Some States using their own authority have chosen to elevate the PN level to Tier 1 for a non-acute MCL in some or all cases. In certain circumstances, some States use this elevated PN in association with other follow-up actions involving agreements with other State and local agencies, to provide a more

comprehensive and immediate response to potential public health threats, or to make the most efficient use of their existing authorities to protect public health. It is not EPA's intent to take this discretion away from the States, or to undermine these cooperative agreements with other State and local agencies. If a State deems that a given situation calls for a more elevated level of PN, or requires a more immediate action to ensure that public health is protected, then they can do so under their own discretion and authority. For example, the Level 2 assessment requirements in § 141.859(b)(4) allow States to require expedited actions or additional actions to ensure that public health is protected.

EPA notes that NCWSs are required, like CWSs, to publish a PN, either a Tier 1, Tier 2, or Tier 3, depending on the violation. Even if they are not required to issue a CCR, NCWS must provide PN in other forms or methods consistent with the requirements of 40 CFR 141.153. States can also direct the PWS to perform additional public health measures (e.g., boil water orders, elevated PNs, etc.) as allowed under SDWA and the authority granted to them by their own legislation similar to EPA's authority under section 1431 of SDWA.

EPA requested comment on whether to require special notice to the public of sanitary defects similar to the special notice requirements for significant deficiencies under the GWR. Most commenters were against including such provision. They stated that it would cause confusion and unnecessary alarm to customers. Several commenters noted that it is not appropriate for sanitary defects under the RTCR to have similar notice requirements as that of significant deficiencies under the GWR. The special notice requirement for significant deficiencies under the GWR only applies to NCWSs since they are not required to send out a CCR. EPA agrees that no special notice of sanitary defects is necessary and is not including such provision in the RTCR.

EPA received comments suggesting modifications to the standard PN and CCR health effects language regarding total coliforms and the treatment technique violations included in the proposed RTCR. EPA has modified the standard health effects language found in Subpart O and Subpart Q of part 141 to make the language consistent with the use of total coliforms in the RTCR as an indicator of a potential pathway through which a contamination can enter the distribution system.

H. Reporting and Recordkeeping

1. Requirements

a. Reporting. In addition to the existing general reporting requirements provided in 40 CFR 141.31, the RTCR requires a PWS to:

- Notify the State no later than the end of the next business day after it learns of an *E. coli*-positive sample.
- Report an *E. coli* MCL violation to the State no later than the end of the next business day after learning of the violation. The PWS must also notify the public in accordance with 40 CFR part 141 subpart Q.
- Report a treatment technique violation to the State no later than the end of the next business day after it learns of the violation. The PWS must also notify the public in accordance with 40 CFR part 141 subpart Q.
- Report monitoring violations to the State within ten days after the system discovers the violation, and notify the public in accordance with 40 CFR part 141 subpart Q.
- Submit completed assessment form to the State within 30 days after determination that the coliform treatment technique trigger has been exceeded.

- Notify the State when each scheduled corrective action is completed for corrections not completed by the time of the submission of the assessment form.
- A seasonal system must certify that it has completed a State-approved start-up procedure prior to serving water to the public.

EPA is adding the submission of the assessment form and the certification of completion of start-up procedure to the reporting requirements under § 141.861 of the RTCR for better clarity and ease of tracking compliance. In the proposed rule, the submission of the assessment form is found only in § 141.859, *Coliform treatment technique requirements for protection against potential fecal contamination*. The inclusion of the submission of the assessment form in § 141.861 does not impose additional requirements beyond those that are imposed by the treatment technique requirements (see section III.E of this preamble, *Coliform Treatment Technique*, for discussion on the treatment technique requirements). Failure to submit the assessment form or the certification is a reporting violation as discussed in section III.F.1.d of this preamble, *Reporting violation*.

b. Recordkeeping. EPA is maintaining the requirements regarding the retention of sample results and records of decisions related to monitoring schedules found in 40 CFR 141.33, and including provisions that address the new requirements of the RTCR pertaining to reduced and increased monitoring, treatment technique, etc. In addition, systems are required to maintain on file for State review the assessment form or other available summary documentation of the sanitary defects and corrective actions taken. Systems are required to maintain these documents for a period not less than five years after completion of the assessment or corrective action. Since systems have to maintain these files no less than five years, which is the maximum period allowed between sanitary surveys (i.e., five years; see 40 CFR 142.16(b)(3) and 40 CFR

142.16(o)(2)), States have the opportunity to review these files during sanitary surveys and/or annual visits. The five-year period is also consistent with the recordkeeping requirements for microbiological analyses under 40 CFR 141.33(a).

The system must also maintain a record of any repeat sample taken that meets State criteria for an extension of the 24-hour period for collecting repeat samples.

2. Key issues raised

EPA received comments that support the reporting and recordkeeping requirements proposed by EPA. Most commenters said that the timeframes are appropriate and are consistent with EPA's practice regarding reporting and recordkeeping requirements in other regulations under SDWA. One commenter, however, said that EPA should standardize the recordkeeping requirements in all its rules, including the RTCR, for a period equal to the compliance cycle (i.e., nine years). The commenter adds that by standardization and being consistent with the compliance cycle, all monitoring and compliance records including corrective actions will be easily maintained, tracked, and available for State's inspections without the confusion of varying recordkeeping durations with different regulations. However, EPA's suite of drinking water regulations addresses different kinds of contaminants with different inherent characteristics, occurrence, and health effects. Because of these differences, monitoring of these contaminants occurs at different frequencies; hence, different reporting and recordkeeping requirements. The reporting and recordkeeping requirements specific to a drinking water regulation are therefore meant to support the implementation of that regulation. If possible, EPA makes every effort to ensure consistency of requirements across the drinking water regulations.

I. Analytical Methods

1. AIP-related method issues

a. Evaluation of currently approved methods. The AIP recommended that the Agency conduct a reevaluation of all the approved methods to ensure continued approval was warranted. In the proposed rule, the Agency identified the Environmental Technology Verification (ETV) program as the preferred mechanism for conducting such an evaluation and solicited comments on the approach.

Key issues raised. While several commenters expressed support for a method reevaluation study conducted through the ETV program, some commenters expressed concern regarding the use of this program. One commenter stated that the reevaluation study should meet criteria established by EPA, not an EPA-contractor, who would receive financial benefit from the method manufacturers for conducting the testing. This commenter further expressed concern with using the ETV program because “the intent of the ETV program was never to certify, approve, guarantee, or warrant analytical technologies.” This commenter also suggested that the ETV program does not have the resources to develop the protocol for the method reevaluation study.

A second commenter expressed concern that the ETV program was established to facilitate incorporation of commercially-ready test kits into the market, which differs from the task of determining what are appropriate performance criteria for SDWA compliance methods. This commenter also expressed concern that the ETV program has not generated rigorous enough product evaluations adequate to support approval of alternative analytical procedures.

Lastly, this commenter also suggested that the ETV studies do not have the same level of independence in protocol development as other third party studies, stating that in ETV studies, reviewers modify the protocol at the beginning of each study, and that for the recent verification

study, there was not a clear discussion between the study organizers and the technical review panel regarding development of the final test protocol.

EPA will take the comments concerning the ETV program into consideration as the Agency develops a final approach to the reevaluation of methods. EPA notes that ETV work is accomplished through cooperative agreements between EPA and private non-profit testing and evaluation organizations. ETV partners verify performance claims but do not endorse, certify or approve technologies. EPA has the regulatory authority and the responsibility to approve/disapprove methods and typically does so based on a review of method performance data generated by third party laboratories. Testing under the ETV program is typically paid for by participating vendors.

ETV expert panels typically include representatives from industry, academia, EPA, and other stakeholders and collaborators. The rigor of an ETV study is determined by the objectives of the study and the resources available. If such a study is conducted, EPA, by virtue of participation in the expert panel, would ensure that the study is rigorous enough to meet the Agency's needs.

EPA held a series of three open technical webinars in fall 2010. Participants recommended the development of a coliform strain library. The Water Research Foundation has funded a project to accomplish this task and the Agency will be monitoring the progress of that work as it considers the appropriate course of action.

b. Review of the ATP protocol. The AIP recommended that the Agency engage stakeholders in a technical dialogue in its review of the Alternate Test Procedure (ATP) microbiological protocol. The proposed rule described how EPA could use the study plan development from the aforementioned method reevaluation study as a starting point for discussions with stakeholders regarding the basis for evaluating new methods. The proposed

rule also explained that the study plan, along with “lessons learned” from the reevaluation study, could be used as a model for a revised ATP protocol.

Key issues raised. One commenter suggested that the protocol used in the method reevaluation study should be used as the revised ATP protocol. EPA intends to consider this recommendation as it decides how to move forward on revising the microbial test protocol.

c. Approval of “24-hour” methods. The AIP recommended that EPA consider the approval of analytical methods that allow more timely (e.g., on the order of 24 hours) results. As expressed in the rule proposal, EPA has concern that the more rapid “24-hour” methods may not have the same recovery rates, especially for stressed or injured organisms, as the historic methods that allow for longer incubation times.

Key issues raised. One commenter suggested that the Agency withdraw approval for the older approved methods that can require longer times to obtain results. EPA intends to consider this recommendation as it decides how to move forward.

d. Elimination of fecal coliforms. As explained in the rule proposal, EPA plans to eliminate all provisions for fecal coliform monitoring under this regulation. No comments were received on this issue. As such, all provisions relating to fecal coliforms are removed in this final rule.

e. Request for comment on other AIP-related method issues. i. Expedited results notification process. The proposed rule requested comment on whether the RTCR should include provisions to ensure a more expedited notification process. The RTCR could, for example, include language requiring that PWSs arrange to be notified of a positive result by their laboratory within 24 hours.

Key issues raised. The Agency received many comments regarding this element of the proposed rule. Many commenters expressed support for this provision, with some States

reporting that this provision is an existing component of their State regulations. Several commenters expressed that given the widespread availability of electronic communication it would be easy for a laboratory to notify the public water system quickly of the results of the sample analyses.

Many comments expressed concern over the ability of the States to enforce such a provision. Additionally, several commenters noted that this provision would hold the water system accountable for the actions of the laboratory, which the public water system does not have immediate control over.

EPA believes that the public is well served by timely reporting of results but recognizes some of the challenges associated with addressing this via regulation. Accordingly, the Agency intends to use guidance documents associated with this regulation to address this issue. Through the guidance documents, the Agency expects to urge public water systems to establish language in their contract with the laboratories requiring that the water system be notified by the laboratory within 24 hours of any positive results.

Additionally, the Agency plans to encourage the certified laboratory community to ensure that laboratories are aware of the importance of timely notification of any positive results to their clients.

ii. Taking repeat samples within 24 hours. During the Advisory Committee meetings, the factors impacting the timeframe between a coliform detection and the collection of the repeat sample were discussed. It was noted that in some cases, repeat samples are not collected for several days after notification of a coliform detection. EPA requested comment in the proposed rule whether the RTCR should require repeat samples be taken within 24 hours of a total coliform-positive with no (or limited) exceptions.

Key issues raised. While some commenters expressed support for such a provision in the final rule, most commenters noted that the final RTCR should retain flexibility around this requirement, as allowed in the 1989 TCR.

Several commenters noted that including such a provision in the final RTCR would create a hardship on systems, with many mentioning that weekend sample collection is a challenge for many small systems. Concern was expressed that this provision in the final rule would result in more monitoring violations but not necessarily change repeat sample collection practice.

Based on consideration of the concerns expressed, EPA is not changing the provision that States may extend the 24-hour limit if the system has a logistical problem in collecting the repeat samples within 24 hours that is beyond its control. See sections III.D of this preamble, *Repeat Samples*, for additional discussion.

2. Other method issues

a. Holding time. In the proposed rule, EPA clarified the language defining when the sample holding time ends. The 1989 TCR states “the time from sample collection to initiation of analysis may not exceed 30 hours,” and this language was clarified in the proposed rule to state “The time from sample collection to initiation of test medium incubation may not exceed 30 hours.”

Key issues raised. Two comments were received on this rule provision, with one commenter explaining that some water systems have a difficult time meeting the 30-hour hold time, and this provision may further impact their ability to meet the holding time. The second commenter stated that the number of coliforms does not likely change in “a 30 minute window” and that this provision will not improve public health.

As explained in the proposed rule, EPA recognizes that this provision may slightly decrease the amount of time that a water system has to get the sample to the lab, by approximately 30 minutes or less. EPA believes the impact of this provision is minimal, as a well managed laboratory will be able to recognize a sample that is received near the end of the holding time and make this sample a priority for analysis.

The inclusion of this provision in the final rule serves to ensure consistency in the analyses of the compliance samples on a national basis and will have a minimal impact on water systems. As such, the provision is included in the final rule.

b. Dechlorinating agent. The proposed rule included a provision that would require the use of a dechlorinating agent when samples of chlorinated water are collected.

Key issues raised. The Agency did not receive any adverse comment to this provision of the proposed regulation. Accordingly, this provision has been included in the final rule. EPA notes that the wording of this provision in the final rule differs slightly from that included in the proposed rule. The wording was changed to clarify that the use of a dechlorinating agent is applicable to water systems that use any type of chlorination (including chloramines) to disinfect their drinking water supplies. The proposed rule did not include language that was specific enough to ensure that this point was clear.

c. Filtration funnels. In the proposed rule, EPA added a footnote to the methods table that clarifies that the funnels used in the membrane filtration procedure should be sterilized by autoclaving, not by using ultraviolet (UV) light. The addition of this provision to the rule makes the rule requirements consistent with what is recommended by the Agency in the *Manual for the Certification of Laboratories Analyzing Drinking Water* (EPA 815-R-05-004, 5th Edition, 2005).

Key issues raised. The Agency only received one comment on this provision, requesting clarification that would allow the use of disposable filtration units that are purchased pre-sterilized by the manufacturer. EPA believes that these units can be appropriate for use in drinking water sample analyses, and therefore has modified the provision to reflect usage of such units. The provision now reads as follows:

All filtration series must begin with membrane filtration equipment that has been sterilized by autoclaving. Exposure of filtration equipment to UV light is not adequate to ensure sterilization. Subsequent to the initial autoclaving, exposure of the filtration equipment to UV light may be used to sanitize the funnels between filtrations within a filtration series. Alternatively, disposable membrane filtration equipment that is pre-sterilized by the manufacturer (i.e., disposable funnel units) may be used.

d. Analytical methods table changes. The proposed rule reflected many modifications to the table of analytical methods to clarify which methods were approved for use under this regulation.

No comments were received on the following changes to the methods table. Accordingly these modifications have been incorporated into the final rule.

- The table is organized by methodology.
- *E. coli* methods are included in the analytical methods table.
- The 18th and 19th editions of *Standard Methods for the Examination of Water and Wastewater* are no longer approved and are not included in the final rule.
- The references to Standard Methods 9221A and 9222A are removed.
- The reference to Standard Methods 9221B is changed to 9221B.1, B.2.
- The reference to Standard Methods 9221D is changed to 9221D.1, D.2.
- The citation for MI agar is changed to EPA Method 1604.
- The table clarifies that Standard Methods 9221 F.1 and 9222 G.1c(1), and 9222 G.1c(2) may be used for *E. coli* analysis.

- The table clarifies the correct formulation for *E. coli* medium with 4-methylumbelliferyl-Beta-D-glucuronide (EC-MUG) broth, when used in conjunction with Standard Methods 9222G.1c(2), through the addition of the following footnote: The following changes must be made to the EC broth with MUG (EC-MUG) formulation: Potassium dihydrogen phosphate, KH₂PO₄ must be 1.5g and 4-methylumbelliferyl-Beta-D-glucuronide must be 0.05 g.
- The table reflects the approval of a modified Colitag method for the simultaneous detection of *E. coli* and other total coliforms.

The proposed rule also contained a provision to allow the use of Standard Methods 9221D in an enumerative format, specifically, in the multiple tube format as described in Standard Methods 9221B.

Key issues raised. One comment was received, stating that the use of Standard Methods 9221D in an enumerative (multiple tube) format should be evaluated through an Alternate Test Procedure (ATP) study or be added to the proposed method reevaluation study. Given that this method is a part of Standard Methods 9221, entitled “Multiple-Tube Fermentation Technique for Members of the Coliform Group,” the Agency believes it is appropriate for this method to be used in an enumerative, multiple tube format. Additionally, as explained in the proposed rule, there have been publications demonstrating that this method is effective in a multiple tube format.

Since use of this method in a multiple-tube format does not change the formulation of the medium, nor the volume of sample analyzed, the Agency has determined that an ATP evaluation is not necessary. Therefore, the provision is included in the final rule.

e. Holding temperature. In the proposed rule, the Agency requested comment as to whether the RTCR should require the samples to be held at 10 degrees Celsius (C) or less during transit.

Key issues raised. Several commenters expressed support for this provision stating that it would improve the integrity of the data collected under this rule. However, many commenters expressed concern that the addition of this provision would cause a hardship, especially to small systems, as it would increase the cost of the sample shipment. Additionally, concern was expressed that this provision would increase the number of “failure to monitor” violations, thereby imposing an enforcement burden on the States.

Based on further consideration of the potential additional burden on both the PWSs and the States, EPA has determined that the provision in the 1989 TCR will stay as is: “Systems are encouraged but not required to hold samples below 10 deg. C during transit.”

Finally, in this final rule, there have been some further changes to the analytical methods table to improve its clarity. Such changes include the addition of the approved online versions of Standard Methods in the analytical methods table and correction of some clerical errors.

J. Systems Under EPA Direct Implementation

Systems falling under direct oversight of EPA (e.g., Tribal systems, PWSs in Wyoming, and PWSs in States that have not yet obtained primacy for the RTCR) where EPA acts as the State, must comply with decisions made by EPA for implementation of the RTCR. Under § 142.16(q), to obtain primacy for the RTCR, States/Tribes are required to demonstrate how they intend to implement the various requirements of the rule; States/Tribes may do so in a manner that maximizes the efficiency of the rule for the States/Tribes and the PWSs while maintaining or increasing the effectiveness of the rule to protect public health. EPA has the same responsibilities when the Agency acts as the State in directly implementing the RTCR. In the proposed RTCR, EPA requested comment on whether to make this explicit in the final RTCR. All commenters who responded to this request for comment were in support of such action. EPA

already has such authority or flexibility in direct implementation situations, both in the 1989 TCR and in all other NPDWRs, but solicited comment and has added this provision to the final rule for the sake of clarity in situations where EPA directly implements the RTCR.

K. Compliance Date

Consistent with SDWA section 1412(b)(10), States and PWSs are given three years after the promulgation of the RTCR to prepare for compliance with the rule. PWSs must begin compliance with the requirements of the RTCR on April 1, 2016, a compliance effective date that is just over three years from promulgation and coincides with quarterly monitoring schedules applicable to many water systems. EPA believes that capital improvements generally are not necessary to ensure compliance with the RTCR. However, a State may allow individual systems up to two additional years to comply with the RTCR if the State determines that additional time is necessary for capital improvements, in accordance with SDWA section 1412(b)(10).

IV. Other Elements of the Revised Total Coliform Rule

A. Best Available Technology

1. Requirements

EPA is making three modifications to the 1989 TCR provisions regarding the best technology, treatment techniques, or other means available for achieving compliance with the MCL for *E. coli* under the RTCR. EPA has re-designated these provisions from 40 CFR 141.63(d) to 141.63(e) and is making the following modifications.

- “Coliforms” in 40 CFR 141.63(d)(1) under the 1989 TCR is replaced with “fecal contaminants” in 40 CFR 141.63(e)(1).

- “Cross connection control” is added to the list of proper maintenance practices for the distribution system in 40 CFR 141.63(e)(3) (formerly 40 CFR 141.63(d)(3)).
- Subparts P, T, and W (filtration and/or disinfection of surface water), and subpart S (disinfection of ground water), are added in 40 CFR 141.63(e)(4) (formerly 40 CFR 141.63(d)(4)).

The Agency is listing the same technology, treatment techniques, or other means available for achieving compliance with the MCL for *E. coli* as provided in § 141.63(e), for small PWSs serving 10,000 or fewer people, as required by SDWA section 1412(b)(4)(E)(ii).

2. Key issues raised

EPA received comments that supported the modifications to the list of best available technologies (BATs). The Agency also received comments suggesting the addition of other items to the list, such as the optional barriers that may qualify systems for reduced monitoring, unidirectional flushing, storage tank inspection, maintenance, and cleaning, and re-pressurization. EPA heard from a few commenters who are against the inclusion of cross connection control in the list of BATs. They stated that it is not appropriate to do so because EPA has not defined cross connection control, and risks associated with cross connection and backflow are being addressed in the research efforts of the Research and Information Collection Partnership (see http://water.epa.gov/lawsregs/rulesregs/sdwa/tcr/regulation_revisions_tcrdsac.cfm#ricp for additional information about the Partnership); hence, they concluded it is premature to include it in the RTCR.

The methods for achieving compliance listed in 40 CFR 141.63(e) represent the technology, treatment technique, and other means which EPA finds to be feasible for purposes of meeting the

MCL for *E. coli*, in accordance with section 1412(b)(4)(E) of SDWA. The RTCR however, is not imposing additional requirements (e.g., disinfection, filtration, etc.) beyond those already addressed by other microbial drinking water regulations such as the Ground Water Rule and the Surface Water Treatment Rules; nor is it imposing specific requirements regarding the use of the other methods such as main flushing programs, cross connection control, etc. PWSs are given the discretion to use the methods in 40 CFR 141.63(e) (if they are not already required to do so), or other methods of their choice (provided they are acceptable to the State), as they see fit for their own systems.

EPA believes that the inclusion of cross connection control to the list of BATs is appropriate given the public health risk associated with unprotected cross connection. Several States already require that PWSs implement a cross connection control program. As discussed in the previous paragraph, the inclusion of cross connection control in 40 CFR 141.63(e) does not impose specific requirements on PWSs to implement a cross connection control program. Rather, it acknowledges that cross connection control can be one of the tools PWSs can use to comply with the *E. coli* MCL.

B. Variances and Exemptions

1. Requirements

EPA is not allowing variances or exemptions to the *E. coli* MCL in § 141.4(a). EPA believes that water that exceeds the MCL for *E. coli* poses an unreasonable risk to public health. Therefore, EPA is not allowing any variances or exemptions to the *E. coli* MCL. EPA is also eliminating the variance provisions in § 141.4(b) under the 1989 TCR that allow systems to demonstrate to the State that the violation of the monthly/non-acute total coliform MCL is due to biofilm and not fecal or pathogenic contamination. This change also results in a parallel change

in § 142.63(b). Since the MCL for total coliforms is eliminated and replaced by a treatment technique, the variance for the presence of biofilms is no longer applicable and allowed under SDWA. Instead, the presence of biofilm is addressed through the assessment and corrective action requirements of the RTCR.

EPA is adding a note to the provision in § 141.4(a) to clarify that small system variances or exemptions for treatment technique requirements in this rule and other rules that control microbial contaminants may not be granted under SDWA section 1415(e)(6)(B) and § 142.304(a). This action reflects the statutory provision within EPA's regulations and adds no new requirements or limitations to any of these rules.

2. Key issues raised

Most commenters support these changes. However, EPA also received comment that supported the retention of the variance for the presence of biofilms. The commenter said that the retention of the biofilm variance would require PWSs to have a biofilm control program in place that will require ongoing assessment and research to determine and address the cause of the biofilms, thereby providing valuable information. Some commenters suggested that if the biofilm variance is removed, EPA should make it clear that the finding of biofilms as the cause of the positive sample during an assessment is not a sanitary defect which requires correction.

As discussed previously in section IV.B.1 of this preamble, *Requirements*, EPA is not allowing variances to the *E. coli* MCL because EPA believes that water which exceeds the MCL for *E. coli* poses an unreasonable risk to public health. Furthermore, retention of the variance for total coliforms is not allowed under SDWA because the MCL for total coliforms is eliminated and replaced by a treatment technique. EPA believes that additional research and information collection will be valuable to learning about the magnitude of the risks from biofilms. However,

research available to date indicates that biofilms can harbor pathogens and result in accumulation of contaminants (Brown and Barker 1999; Szewzyk *et al.* 2000; Berry *et al.* 2006; Långmark *et al.* 2007), and considering it a sanitary defect is warranted in some cases. Also, persistent biofilms that cause continued total coliform presence compromises the value of total coliforms as an indicator of potential pathways of contamination. If biofilm is determined to be the cause of the total coliform-positive samples that triggered an assessment, the PWS is encouraged to work with the State to determine the right course of action to address the biofilms. Under the RTCR, States have the discretion to determine if the completed assessment and corrective action are adequate. The State can use this discretion in addressing instances of biofilm presence and determining the extent of biofilm problems in the distribution system and the need to address them. When a system has an ongoing biofilm problem that continues to cause total coliform-positive samples, the system and the State can continue to take action until the biofilm problem is resolved.

C. Revisions to Other NPDWRs as a Result of the RTCR

EPA recognizes that there are linkages among monitoring requirements between the 1989 TCR and other NPDWRs. For instance, under the Surface Water Treatment Rule (SWTR) (USEPA 1989b, 54 FR 27486, June 29, 1989) and the Stage 1 Disinfectants and Disinfection Byproducts Rule (Stage 1 DBPR) (USEPA 1998a, 63 FR 69389, December 16, 1998), the residual disinfectant monitoring must be conducted at the same time and location at which total coliform samples are taken, as required. Under the SWTR, high measurements of turbidity in an unfiltered subpart H system (i.e., a system using surface water or ground water under the influence of surface water) trigger additional total coliform samples; and compliance with the total coliform MCL under the 1989 TCR is one of the criteria for a PWS to avoid filtration.

Under the GWR, 1989 TCR distribution system monitoring results determine whether a system is required to conduct source water monitoring.

For the criteria for avoiding filtration in the SWTR (§ 141.71(b)(5)), the Agency is clarifying that unfiltered systems must continue to meet the *E. coli* MCL promulgated with the final RTCR at § 141.63(c) in order to remain unfiltered. The changes to § 141.71(b)(5) provides for replacement of the (acute) total coliform MCL at § 141.63(b) with the *E. coli* MCL at § 141.63(c) at the compliance date of the RTCR. Although the name of the MCL has changed, the determination of the *E. coli* MCL remains basically the same as that for the (acute) total coliform MCL in § 141.63(c), with the only changes being those that were made to address the advisory committee recommendations and the public comments.

After considering other possible linkages between the RTCR and the SWTR, GWR, Stage 1 DBPR, Stage 2 DBPR (USEPA 2006e, 71 FR 388, January 4, 2006), and Airline Drinking Water Rule (USEPA 2009), EPA has concluded that the only other necessary revision to these NPDWRs is to update the references to the 1989 TCR at 40 CFR 141.21, which is superseded by 40 CFR part 141 subpart Y beginning April 1, 2016. The monitoring requirements themselves are not changing as a result of the RTCR. Residual disinfectant samples must still be taken at the same time and location at which total coliform samples are taken under the RTCR. High measurements of turbidity under the SWTR would still result in additional total coliform samples. Results of total coliform monitoring under the RTCR would still be a trigger for the GWR. Although there are changes to the dual-purpose sampling requirement (i.e., one sample to satisfy both the repeat monitoring requirement of the RTCR and the triggered source water monitoring requirement of the GWR), these changes are addressed in the RTCR and not in the GWR (see section III.D of this preamble, *Repeat Samples*, for further discussion on dual-purpose

sampling). Comments received on dual-purpose sampling are also discussed in section III.D of this preamble, *Repeat Samples*.

EPA also received comments regarding the relationship between source water evaluations under the GWR and assessments under RTCR; those comments are addressed in section III.E.2 of this preamble, *Assessment*.

The RTCR is also not changing the existing sanitary survey requirements established under the IESWTR and the GWR. However, the RTCR is adding the special monitoring evaluation that States must conduct at systems serving 1,000 or fewer people during the sanitary survey. These evaluations are not expected to significantly increase the burden to conduct sanitary surveys because of the relatively simple nature of these systems and their monitoring requirements.

EPA did not receive any other substantial comments regarding the relationships between RTCR and other NPDWRs.

EPA recognizes that there are sections of part 141 that will no longer be applicable after the RTCR compliance effective date. EPA intends to review and update these sections in the future.

D. Storage Facility Inspection

In the proposed RTCR, EPA discussed the potential public health implications associated with poorly maintained storage facilities (such as those associated with significant sediment accumulation inside the tank and the presence of breaches). EPA requested comment and supporting information regarding the current status of storage tanks and their inspection as implemented by individual States and PWSs. Some of the information EPA requested comment on included the state and condition of tanks that have been cleaned and inspected, costs of storage tank inspection and cleaning, the frequency of inspection and cleaning, and how public

health can be better protected. Based on the comments and information that EPA received, the Agency is considering the need for inspection requirements for finished water storage facilities that would help mitigate potential public health risks if PWSs do not inspect their storage facilities as recommended by industry guidance (e.g., American Water Works Association (AWWA) Manual 42). EPA plans to provide further information on the results of its consideration of this issue in a future notice.

V. State Implementation

SDWA establishes requirements that States or eligible Indian Tribes must meet to assume and maintain primary enforcement responsibility (primacy) to implement national primary drinking water regulations. This section describes the requirements that States must meet to maintain primacy under the RTCR, including adoption of drinking water regulations that are no less stringent than the RTCR and meeting recordkeeping and reporting requirements. This section also provides an update on the Safe Drinking Water Information System (SDWIS) revisions that EPA is developing to facilitate the implementation of RTCR.

A. Primacy

1. Requirements

States are required to adopt or maintain requirements that are at least as stringent as all of the sections of 41 CFR part 141 that are revised or added by the RTCR. SDWA provides two years after promulgation of the RTCR (plus up to two more years if the Administrator approves) for the State to adopt their regulations. States may adopt more stringent requirements (e.g., requiring all systems to conduct routine monthly monitoring). Many States have used this authority in the past to improve public health protection and/or simplify implementation.

EPA grants interim primary enforcement authority for a new or revised regulation during the period in which EPA is making a determination with regard to primacy for that new or revised regulation. States that have primacy (including interim primacy) for every existing NPDWR already in effect may obtain interim primacy for the RTCR, beginning on the date that the State submits the application for this rule to EPA, or the effective date of its revised regulations, whichever is later. A State that wishes to obtain interim primacy for future NPDWRs must obtain primacy for this rule.

EPA regulations at 40 CFR part 142 contain the program implementation requirements for States to obtain primacy for the public water supply supervision program as authorized under SDWA section 1413. In addition to adopting rule requirements that are at least as stringent as the requirements of the RTCR, and basic primacy requirements specified in 40 CFR part 142, States are required to adopt special primacy provisions pertaining to each specific regulation where State implementation of the rule involves activities beyond general primacy provisions. States must include these regulation-specific provisions in their application for approval of any program revision. States must also continue to meet all other conditions of primacy for all other rules in 40 CFR part 142.

The RTCR provides States with flexibility to implement the requirements of the rule in a manner that maximizes the efficiency of the rule for the States and water systems while increasing the effectiveness of the rule to protect public health. To ensure an effective and enforceable program under the RTCR, the State primacy application for RTCR must include a description of how the State will meet the following special primacy provisions contained in the RTCR at 40 CFR part 142:

- Baseline and Reduced Monitoring Provisions – The State primacy application must indicate

what baseline and reduced monitoring provisions of the RTCR the State will adopt and describe how the State will implement the RTCR in these areas so that EPA can be assured that implementation plans meet the minimum requirements of the rule.

- Sample Siting Plans - States must describe the frequency and process used to review and revise sample siting plans in accordance with 40 CFR 141, subpart Y to determine adequacy.
- Reduced Monitoring Criteria – The primacy application must indicate whether the State will adopt the reduced monitoring provisions of the RTCR (e.g., reduced monitoring provisions for ground water systems serving 1,000 or fewer people, including provisions on dual purpose sampling). If the State adopts the reduced monitoring provisions, it must describe the specific types or categories of water systems that will be covered by reduced monitoring and whether the State will use all or a reduced set of the optional criteria. For each of the reduced monitoring criteria, both mandatory and optional, the State must describe how the criteria will be evaluated to determine when systems qualify.
- Assessments and Corrective Actions – States must describe their process to implement the new assessment and corrective action phase of the rule. The description must include how the State will ensure that Level 2 assessments are more comprehensive than Level 1 assessments, examples of sanitary defects, examples of assessment forms or formats, and methods that systems may use to consult with the State on appropriate corrective actions.
- Invalidation of routine and repeat samples collected under the RTCR – States must describe their criteria and process to invalidate total coliform-positive and *E. coli*-positive samples under the RTCR. This includes criteria to determine if a sample was improperly processed by the laboratory, reflects a domestic or other non-distribution system plumbing problem or reflects circumstances or conditions that do not reflect water quality in the distribution

system.

- Approval of individuals allowed to conduct RTCR Level 2 assessments – States must describe their criteria and process for approval of individuals allowed to conduct RTCR Level 2 assessments.
- Special monitoring evaluation – States must describe how they will perform special monitoring evaluations during sanitary surveys for ground water systems serving 1,000 or fewer people to determine whether systems are on an appropriate monitoring schedule.
- Seasonal systems – States must describe how they will identify seasonal systems, how they will determine when systems on less than monthly monitoring must monitor, and what will be the seasonal system start-up provisions.
- Additional criteria for reduced monitoring – States must describe how they will require systems on reduced monitoring to demonstrate, where appropriate:
 - Continuous disinfection entering the distribution system and a residual in the distribution system.
 - Cross connection control.
 - Other enhancements to water system barriers.
- Criteria for extending the 24-hour period for collecting repeat samples – If the State elects to use a set of criteria in lieu of case-by-case decisions, they must describe the criteria they will use to waive the 24-hour time limit for collecting repeat samples after a total coliform-positive routine sample, or to extend the 24-hour limit for collection of samples following invalidation. If the State elects to use only case-by-case waivers, the State does not need to develop and submit criteria.

2. Key issues raised

Commenters generally supported the inclusion of these activities in the primacy application and emphasized the importance of the flexibility and discretion that this approach provides for States to build on existing authorities of the 1989 TCR and focus on systems with the greatest need. They suggested that EPA allow States as much flexibility and discretion as possible to design their approach to implementing the RTCR, including how to address seasonal water systems, qualifications of assessors, the content of sample siting plans, and compliance with multiple rules (e.g., coordination between 1989 TCR / RTCR and GWR compliance), and how to consider multiple Level 1 assessments where the cause of the first Level 1 assessment has been identified and corrected. However, some commenters suggested removal of some of the special primacy requirements, such as those regarding seasonal system startup procedures and how the States will review sample siting plans, implement the assessment and corrective action phase, and determine who is approved to conduct Level 2 assessments. EPA is maintaining these primacy requirements in the RTCR because they provide the States with the flexibility to design their programs to fit their own needs without prescriptive, one-size-fits-all requirements. Describing how the State will accomplish them in the primacy application assures that consumers nationwide are receiving adequate and comparable public health protection under the rule.

EPA also requested comment on whether it is appropriate to have States describe their criteria for waiving or extending the 24-hour limit to collect repeat samples as a special primacy condition, or instead have States keep records of decisions to waive and/or extend the 24-hour limit. The majority of the commenters supported the former option as it reduces paperwork burden and adds flexibility to the implementation of the RTCR. EPA concurs and added the waiver or extension of the 24-hour limit to the special primacy requirements as an option for

States that would rather describe their criteria for waiving or extending the 24-hour limit in their primacy application, instead of having to make the decision on a case-by-case basis. States that elect to use only case-by-case waivers do not need to develop and submit criteria.

B. State Recordkeeping and Reporting and SDWIS

1. Recordkeeping

The current regulations in 40 CFR 142.14 require States with primacy to keep records, including: analytical results to determine compliance with MCLs, maximum residual disinfectant levels (MRDLs), and treatment technique requirements; PWS inventories; State approvals; enforcement actions; and the issuance of variances and exemptions. Consistent with the recordkeeping requirements of the current regulations, the RTCR requires States to keep records and supporting information for each of the following decisions or activities for five years:

- Any case-by-case decision to waive the 24-hour time limit for collecting repeat samples after a total coliform-positive routine sample, or to extend the 24-hour limit for collection of samples following invalidation.
- Any decision to allow a system to waive the requirement for three routine samples the month following a total coliform-positive sample. The record of the waiver decision must contain all the items listed in §§ 141.854(j) and 141.855(f) of the RTCR.
- Any decision to invalidate a total coliform-positive sample. If the State decides to invalidate a total coliform-positive sample as provided in § 141.853(c)(1) of the RTCR, the record of the decision must contain all the items listed in that paragraph.

Also, consistent with the recordkeeping requirements of the current regulations, under the RTCR States must retain records of each of the following decisions in such a manner that each system's current status may be determined at any time:

- Any decision to reduce the total coliform monitoring frequency for a community water system serving 1,000 or fewer people to less than once per month, as provided in § 141.855(d) of the RTCR; and what the reduced monitoring frequency is. A copy of the reduced monitoring frequency must be provided to the system.
- Any decision to reduce the total coliform monitoring frequency for a non-community water system using only ground water and serving 1,000 or fewer people to less than once per quarter, as provided in § 141.854(e) of the RTCR, and what the reduced monitoring frequency is. A copy of the reduced monitoring frequency must be provided to the system.
- Any decision to reduce the total coliform monitoring frequency for a non-community water system using only ground water and serving more than 1,000 persons during any month the system serves 1,000 or fewer people, as provided in § 141.857(d) of the RTCR. A copy of the reduced monitoring frequency must be provided to the system.
- Any decision to waive the 24-hour limit for taking a total coliform sample for a public water system that uses surface water, or ground water under the direct influence of surface water, and that does not practice filtration in accordance with part 141, subparts H, P, T, and W, and that measures a source water turbidity level exceeding 1 nephelometric turbidity unit (NTU) near the first service connection.
- Any decision to allow a public water system to forgo *E. coli* testing on a total coliform-positive sample if that system assumes that the total coliform-positive sample is *E. coli*-positive.

The RTCR also adds the following new recordkeeping requirement:

- States must keep records and supporting information regarding completed and approved RTCR assessments, including reports from the system that corrective action has been completed, for five years.

2. Reporting

EPA currently requires at 40 CFR 142.15 that States report to EPA information such as violations, variance and exemption status, and enforcement actions. The RTCR requires States to develop and maintain a list of public water systems that the State is allowing to monitor less frequently than once per month for community water systems or less frequently than once per quarter for non-community water systems, including the compliance date (the date that reduced monitoring was approved) of the reduced monitoring requirement for each system.

3. SDWIS

EPA has begun to plan and develop the next version of SDWIS, SDWIS Next Gen, which will provide improved capabilities to update the system when there are new rule requirements and that enables more efficient data sharing among systems, laboratories, States, and EPA. EPA has established a governance structure to allow States to provide input on SDWIS Next Gen and begin identifying and prioritizing necessary system functions. Developing the portions of the system that are needed for implementing RTCR is a high priority. EPA remains committed to completing revisions to SDWIS that will facilitate implementation of RTCR and to completing them well in advance of the effective date of the rule.

4. Key issues raised

Many commenters emphasized the importance of developing revisions to SDWIS sufficiently in advance of the effective date of the rule to allow for efficient, effective, and consistent implementation, tracking, recordkeeping, and reporting. As indicated above, EPA has already

begun planning and development of SDWIS Next Gen to incorporate changes necessary to implement RTCR. EPA plans to complete the revisions necessary to implement RTCR well in advance of the RTCR effective date. Commenters also noted the advisory committee recommendation to develop metrics for evaluating the effectiveness of RTCR. Identifying metrics and incorporating them into SDWIS Next Gen will be part of the process completed by the governance structure with the input of stakeholders.

Some commenters objected to the requirement for States to maintain lists of systems on reduced monitoring and information on decisions on sample invalidations and waivers of time limits. EPA notes that these requirements also existed under the 1989 TCR and are not new under the RTCR. These requirements, and the requirements to maintain other information such as regarding assessments and review of seasonal system startup procedures, will be considered in the design of SDWIS Next Gen and incorporated to the extent possible to help States efficiently manage their implementation requirements.

Commenters also expressed the need for guidance to help States implement rule requirements regarding annual site visits for systems on annual monitoring, review of system RTCR monitoring frequency during sanitary surveys, review of seasonal system startup procedures, and identification of qualified assessors for Level 2 assessments. EPA plans to work with States to develop the necessary changes in implementation guidance well before the effective date of the RTCR.

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

This section summarizes the economic analysis (EA) for the final RTCR. The EA is an assessment of the benefits, both health and non-health-related, and costs to the regulated community of the final regulation, along with those of regulatory alternatives that the Agency

considered. EPA developed the EA for the RTCR to meet the requirement of SDWA section 1412(b)(3)(C) for a Health Risk Reduction and Cost Analysis (HRRCA), as well as the requirements of Executive Order 12866, Regulatory Planning and Review, and Executive Order 13563, Improving Regulation and Regulatory Review, under which EPA must estimate the costs and benefits of the rule. The full EA for the final RTCR (RTCR EA) (USEPA 2012a) includes additional details and discussion on the topics presented throughout this section of the preamble. It is available in the docket (Docket ID No. EPA-HQ-OW-2008-0878) and is also published on the government's Web site at <http://www.regulations.gov>.

SDWA section 1412(b)(3)(C) requires that the HRRCA for a NPDWR take into account the following seven elements: (1) quantifiable and nonquantifiable health risk reduction benefits; (2) quantifiable and nonquantifiable health risk reduction benefits from reductions in co-occurring contaminants; (3) quantifiable and nonquantifiable costs that are likely to occur solely as a result of compliance; (4) incremental costs and benefits of rule options; (5) effects of the contaminant on the general population and sensitive subpopulations including infants, children, pregnant women, elderly, and individuals with a history of serious illness; (6) any increased health risks that may occur as a result of compliance, including risks associated with co-occurring contaminants; and (7) other relevant factors such as uncertainties in the analysis and factors with respect to the degree and nature of risk. A summary of these elements is provided in this section of the preamble, and a complete discussion can be found in the RTCR EA.

Both benefit and cost measures are adjusted using social discounting. In social discounting, future values of a rule's or policy's effects are multiplied by discount factors. The discount factors reflect both the amount of time between the present and the point at which these events occur and the degree to which current consumption is more highly valued than future

consumption (USEPA 2000a). This process allows comparison of cost and benefit streams that are variable over a given time period. EPA uses social discount rates of both three percent and seven percent to calculate present values from the stream of benefits and costs and also to annualize the present value estimates. Historically, the use of three percent is based on after tax rates of return to consumers on relatively risk-free financial instruments, while seven percent is an estimate of average economy-wide before-tax rate of return to incremental private investment generally. For further information, see USEPA 2000a and OMB 1996.

The time frame used for both benefit and cost comparisons in this rule is 25 years. This time interval accounts for rule implementation activities occurring soon after promulgation (e.g., States adopting the criteria of the regulation) and the time for different types of compliance actions (e.g., assessments and corrective actions) to be realized up through the 25th year following rule promulgation. In the RTCR EA, EPA also presents the undiscounted stream of benefits and costs over the 25-year time frame in constant 2007 dollars (2007\$).

The benefits described in this section are discussed qualitatively, and reductions in occurrence of total coliforms and *E. coli* and in Level 2 assessments are used as indicators of positive benefits. EPA was unable to quantify health benefits for the RTCR because there are insufficient data reporting the co-occurrence in a single sample of fecal indicator *E. coli* and pathogenic organisms. In addition, the available fecal indicator *E. coli* data from the Six-Year Review 2 dataset (USEPA 2012a) described in this preamble were limited to presence-absence data because the 1989 TCR requires only the reporting of presence or absence of fecal indicator *E. coli* using EPA-approved standard methods. However, as discussed in chapter 6 of the RTCR EA, even though health benefits could not be directly quantified, the potential benefits from the RTCR include avoidance of a full range of health effects from the consumption of fecally

contaminated drinking water, including the following: acute and chronic illness, endemic and epidemic disease, waterborne disease outbreaks, and death. Since fecal contamination may contain waterborne pathogens including bacteria, viruses, and parasitic protozoa, in general, a reduction in fecal contamination should reduce the risk from all of these contaminants.

The net costs of the rule stem mostly from the new assessment and corrective action requirements as well as the revised monitoring provisions described earlier in this preamble. The costs discussed in this section are presented as annualized present values in constant 2007\$.

This section of the preamble includes elements as follows: (A) Regulatory Options Considered, (B) Major Sources of Data and Information Used in Supporting Analyses, (C) Occurrence and Predictive Modeling, (D) Baseline Profiles, (E) Anticipated Benefits of the RTCR, (F) Anticipated Costs of the RTCR, (G) Potential Impact of the RTCR on Households, (H) Incremental Costs and Benefits, (I) Benefits from Simultaneous Reduction of Co-occurring Contaminants, (J) Change in Risk from Other Contaminants, (K) Effects of Fecal Contamination and/or Waterborne Pathogens on the General Population and Sensitive Subpopulations, (L) Uncertainties in the Benefit and Cost Estimates for the RTCR, (M) Benefit Cost Determination for the RTCR, (N) Comments Received in Response to EPA's Requests for Comment, and (O) Other Comments Received by EPA.

A. Regulatory Options Considered

EPA evaluated the following three regulatory options as part of this revised rule: (1) the 1989 TCR option, (2) the RTCR option (today's final rule), and (3) an Alternative option. EPA discusses the three regulatory options briefly in this preamble and in greater detail in chapter 3 of the RTCR EA.

First, the 1989 TCR option reflects EPA's understanding of how the 1989 TCR is currently being implemented. That is, the 1989 TCR option is assumed to include "status quo" PWS and State implementation practices. Next, the RTCR option is based on the provisions of this final rule as described in detail in section III of this preamble, *Requirements of the Revised Total Coliform Rule*. Third, the Alternative option parallels the RTCR in most ways but includes variations of some of the provisions that were discussed by the advisory committee before they reached consensus on the recommendations in their AIP, which served as the basis for the proposed and final rules.

The Alternative option differs from the RTCR option in two ways. First, under the Alternative option, at the compliance date all PWSs are required to sample monthly for an initial period until they meet the eligibility criteria for reduced monitoring. EPA assumes that eligibility for reduced monitoring is determined during the next sanitary survey following the RTCR compliance date. This more stringent approach differs from the RTCR option that allows PWSs to continue to monitor at their current frequencies (with an additional annual site visit or voluntary Level 2 assessment requirement for PWSs wishing to remain on annual monitoring) until they are triggered into an increased sampling frequency. Second, under the Alternative option, no PWSs are allowed to reduce monitoring to an annual basis. EPA defined the Alternative option this way and included it in the RTCR EA to assess the relative impacts of a more stringent rule and to better understand the balance between costs and public health protection. EPA wishes to emphasize that it is not adopting the Alternative Option, but is providing cost and benefit information on it as a point of comparison with the final rule as promulgated.

To understand the relative impacts of the options, EPA gathered available data and information to develop and provide input into an occurrence and predictive model. EPA estimated both baseline conditions and changes to these conditions anticipated to occur over time as a result of these revised rule options. The analysis is described in more detail in the RTCR EA.

B. Major Sources of Data and Information Used in Supporting Analyses

This section of the preamble briefly discusses the data sources that EPA used in its supporting analyses for the RTCR. For a more detailed discussion, see chapter 4 of the RTCR EA.

1. Safe Drinking Water Information System Federal Version data

Safe Drinking Water Information System Federal Version (SDWIS/FED) is EPA's national regulatory compliance database for the drinking water program and is the main source of PWS inventory and violation data for the RTCR baseline. SDWIS/FED contains information on each of the approximately 155,000 active PWSs as reported by primacy agencies, EPA Regions, and EPA headquarters personnel. SDWIS/FED includes records of MCL violations and monitoring and reporting violations (both routine and repeat and minor and major). It does not include sample results. It also contains information to characterize the US inventory of PWSs including system name and location, retail population served, source water type (ground water (GW), surface water (SW), or ground water under the direct influence of surface water (GWUDI)), disinfection status, and PWS type (community water system (CWS), transient non-community water system (TNCWS), and non-transient non-community water system (NTNCWS)).

To create the PWS and population baseline, EPA used the fourth quarter of SDWIS/FED 2007 (USEPA 2007b), which was the most current PWS inventory data available when EPA

began developing the RTCR EA. These data represent all current, active PWSs and the population served by these systems.

EPA also used the MCL violation data from SDWIS/FED to validate model predictions for systems serving 4,100 or fewer people and to predict *E. coli* (or “acute,” under the 1989 TCR) MCL violations (1989 TCR, RTCR, and Alternative option), total coliform (non-acute or monthly) MCL violations (1989 TCR), and Level 1 and Level 2 assessment triggers (RTCR and Alternative option) for systems serving more than 4,100 people.

2. Six-Year Review 2 data

Through an Information Collection Request (ICR) (USEPA 2006b), States voluntarily submitted electronically available 1989 TCR monitoring data¹ (sample results) that were collected between January 1998 and December 2005. EPA requested the 1989 TCR monitoring results with the intent of conducting analyses and developing models to assess the potential impacts of changes to the 1989 TCR. EPA received data from 46 States, Tribes, and territories. A Data Quality Report (USEPA 2010c) describes how the 1989 TCR monitoring data were obtained, evaluated, and modified where necessary to make the database internally consistent and usable for analysis. Exhibit 2.1 in the Data Quality Report provides a complete list of States or territories that submitted data and a description of the use of these data.

In this EA, EPA included data from 37 primacy agencies (35 States and 2 Tribes). Records included data for:

- PWS information (system type, population served, source water type)
- Sample type (routine, repeat, special purpose)
- Analytical result

¹ This refers to results of monitoring conducted pursuant to the 1989 TCR, not results from the year 1989.

- Sampling location – entry point, distribution system and, for repeat samples, original location, downstream, upstream, and other
- Analytical method
- Disinfectant residual data collected at TCR monitoring sites

As discussed in greater detail in section 4.2.2.1 of the RTCR EA, EPA used 2005 data exclusively in the analyses supporting the RTCR because the 2005 data set was the most complete year of data among the Six-Year Review 2 data. The 2005 data was also the most recent data available suggesting that it may be the most representative of present conditions.

The Six-Year Review 2 data also informed EPA’s assumptions regarding the proportions of ground water systems serving 1,000 or fewer people that sample monthly, quarterly, or annually.

3. Other information sources

Additional data and information sources included the Economic Analysis for the Ground Water Rule (GWR EA) (USEPA 2006a), the *Technology and Cost Document for the Revised Total Coliform Rule* (RTCR T&C document) (USEPA 2012b), the US Census data, and the knowledge and experience of stakeholders representing industry, States, small systems, and the public.

The GWR EA provided occurrence information on *E. coli* in the source water of ground water PWSs for modeling the triggered monitoring component of GWR and informed the assumptions on the distribution of corrective actions taken in response to the presence of *E. coli* in the source water. As discussed in section VI.C of this preamble, *Occurrence and Predictive Modeling*, the model developed for this economic analysis considers the effect of GWR both before and during implementation of the RTCR. The RTCR T&C document included estimates of unit costs for the major components of the RTCR that were obtained from the advisory

committee technical workgroup and vendors, including labor, monitoring, assessments, and corrective actions.

US Census data were used to estimate population per household and to characterize sensitive subpopulations. Lastly, knowledge and experience from stakeholders helped to inform the assumptions that were made for the analysis.

A more detailed discussion of these data sources and how EPA used them are included in the RTCR EA.

C. Occurrence and Predictive Modeling

EPA used the data to develop an occurrence and predictive model for PWSs serving 4,100 or fewer people based primarily on the 2005 Six-Year Review 2 data. The model predicts changes in total coliform and *E. coli* occurrence, Level 1 and Level 2 assessments (based on simulated monitoring results), corrective actions, and violations over time. EPA developed another simpler predictive model for PWSs serving more than 4,100 people that predicts Level 1 and Level 2 assessments (based on 2005 violation data from SDWIS/FED), corrective actions, and violations over time, but not total coliform and *E. coli* occurrence. EPA modeled systems serving more than 4,100 people separately because the Six-Year Review 2 data for larger PWSs were not as robust as the data for the smaller systems. In addition, while the RTCR includes new monitoring requirements for PWSs serving 4,100 people or fewer, monitoring requirements for systems serving greater than 4,100 people remain essentially unchanged from the 1989 TCR. This section briefly discusses the structures of each of the two models and how they used available data, information, and assumptions to make predictions over time resulting from the regulatory options.

Chapter 5 of the RTCR EA includes a more detailed description of the occurrence and predictive model used for PWSs serving 4,100 or fewer people, and the other simpler predictive model used for PWSs serving greater than 4,100 people.

1. Model used for PWSs serving $\leq 4,100$ people

The occurrence and predictive model used for PWSs serving 4,100 or fewer people has two components. The first component of the model characterized how the presence or positive rates of total coliform and *E. coli* detections vary across the population of small (serving 4,100 or fewer people) public water systems in the US. These rates vary by the type of sample (routine or repeat), by analyte (total coliforms or *E. coli*), and by system type (CWS, NCWS, or TNCWS) and size. The second component of the model used the total coliform and *E. coli* occurrence distributions to simulate a set of nationally-representative systems within the context of the three regulatory options (1989 TCR, RTCR, and Alternative) to predict changes in total coliform and *E. coli* occurrence, triggers, assessments, corrective actions over time, and violations.

The model assumed that the national occurrence of total coliforms and *E. coli* has reached a steady state in recent years under the 1989 TCR. It assumed that cycles of normal deterioration and repair/replacement are occurring at the individual system level, but the numbers of violations at the national level have remained relatively unchanged. This assumption is based on evaluation of SDWIS/FED violation data. Exhibit VI-1 presents the number of PWSs with violations from 2001-2007 under the 1989 TCR which shows that national violation rates have remained relatively steady over recent years. The RTCR will affect this steady state, likely resulting in a reduction of the underlying occurrence and associated violations.

Exhibit VI-1 Number of PWSs with Violations by System Type (2001 – 2007)

PWS Type	Year						
	2001	2002	2003	2004	2005	2006	2007
Acute MCL Violations							
CWS	143	144	185	171	151	171	171
NTNCWS	51	53	70	58	65	68	45
TNCWS	261	278	322	351	349	361	295
All	455	475	577	580	565	600	511
Non-Acute MCL Violations							
CWS	2,074	2,110	2,204	2,314	2,196	2,095	1,996
NTNCWS	601	679	725	750	753	735	655
TNCWS	2,707	2,934	3,036	3,132	3,039	3,244	3,209
All	5,382	5,723	5,965	6,196	5,988	6,074	5,860

Note: PWSs counts are of systems that had at least one violation during the year.

Source: SDWIS/FED annual data for period ending 3rd quarter 2001-2007. OH, US territories, Tribal PWS data excluded.

Before the RTCR goes into effect, GWR implementation begins and is also expected to affect the steady state. To estimate the effects that GWR implementation is expected to have on present steady state conditions, EPA used the occurrence and predictive model to simulate five years of implementation of the 1989 TCR with the GWR, which became effective in December 2009. EPA assumed these five years to account for the approximately two years before the expected promulgation date of the final RTCR and an additional three years after that until the RTCR effective date. The assumptions made to account for the GWR are described in detail in the in the RTCR EA and summarized in Exhibit VI-2.

Exhibit VI-2 Summary of Major Assumptions for Simulating GWR Implementation

GWR Provision	Modeling Approach / Assumption
<p>Triggered Monitoring: Ground water systems not providing 4-log treatment for viruses that have total coliform-positive samples under the 1989 TCR are required to take source water samples and test for a fecal indicator. If the sample is positive, they must take an additional 5 source water samples (unless the State requires corrective action). If any of these is positive, they must conduct corrective action.</p>	<p>Current model used same probabilities used in GWR EA (USEPA 2006a) to predict whether source water samples will be <i>E. coli</i>-positive.</p> <p>Ground water systems required to conduct corrective action due to monitoring results will either install disinfection or implement a nondisinfecting corrective action as described in the RTCR EA.</p> <p>Ground water systems installing disinfection will draw from the probability distributions for total coliforms and <i>E. coli</i> for disinfected systems for the remainder of analysis.</p> <p>Ground water systems implementing a nondisinfecting corrective action will experience no positive samples for the remainder of the year plus two additional years and will experience a 75¹ percent reduction in occurrence for five additional years.</p>
<p>Sanitary Surveys: GWR includes Federal sanitary survey requirements for all ground water systems, and requires States to perform regular comprehensive sanitary surveys including eight critical elements.</p>	<p>Model did not explicitly simulate sanitary surveys or their results. Rather, it assumed that the new sanitary survey provisions will result in 10 percent² reduced occurrence of total coliforms universally for entire analysis.</p>
<p>Compliance Monitoring: Ground water systems that provide 4-log treatment for viruses must demonstrate that they are providing this level of treatment by conducting compliance monitoring.</p>	<p>Model did not explicitly simulate compliance monitoring. Rather, it assumed that the provision will result in 10 percent³ reduced occurrence of total coliforms for those ground water systems that are conducting compliance monitoring once assumed 4-log treatment for viruses begins.</p>

^{1,2,3} Assumption reflects EPA best professional judgment.
Source: RTCR EA (USEPA 2012a) as informed by GWR EA (USEPA 2006a).

Actual reductions in occurrence from the implementation of GWR requirements may differ from what is presented here. However, based on assumptions used in this model, the analysis of how the RTCR and Alternative option perform relative to each other are not affected.

In addition to capturing the effect of implementation of GWR requirements with the 1989 TCR for a five-year period of analysis, the model captures an additional 25 years with the 1989 TCR, the RTCR option, and the Alternative option. Along with changes in total coliform and *E.*

coli occurrence, the model predicts behavioral changes: the number of Level 1 and Level 2 assessments (and associated Level 1 or Level 2 corrective actions) to be performed, further resulting adjustments to occurrence, and changes in sampling regimens as systems qualify for reduced monitoring requirements. The assumptions used to simulate RTCR implementation are detailed in the RTCR EA and summarized in Exhibit VI-3.

Exhibit VI-3 Summary of Major Assumptions for Simulating RTCR Implementation

RTCR Provision	Modeling Approach / Assumption
Level 1 Assessment	<p>Model simulates sampling and sampling results and determines which PWSs will be triggered to conduct an assessment.</p> <p>Sanitary defects are found in 10 percent¹ of assessments (represents net increase over the 1989 TCR).</p> <p>All sanitary defects are corrected. Model selects from distribution of potential corrective actions as explained in chapter 7 of the RTCR EA (USEPA 2012a).</p> <p>PWSs implementing a corrective action as a result of a Level 1 assessment experience no positive samples for the remainder of the year plus one additional year and will experience 50 percent² reduction in occurrence for three additional years.</p>
Level 2 Assessment	<p>Model simulates sampling and sampling results and determines which PWSs will be triggered to conduct an assessment.</p> <p>Sanitary defects will be found in 10 percent³ of assessments (represents net increase over the 1989 TCR).</p> <p>All sanitary defects are corrected. Model selects from distribution of potential corrective actions as explained in chapter 7 of the RTCR EA (USEPA 2012a).</p> <p>PWSs implementing a corrective action as a result of a Level 2 assessment will experience no positive samples for the remainder of the year plus two additional years and will experience 75 percent⁴ reduction in occurrence for five additional years.</p>

^{1,3} Assumption based on conversation with State representatives with on-the-ground experience.

^{2,4} Assumption reflects EPA best professional judgment.

Note: EPA recognizes that there is a large uncertainty with the assumptions. Sensitivity analyses showed that the fundamental conclusions of the economic analysis do not change over a wide range of assumptions tested.

Source: RTCR EA (USEPA 2012a)

EPA made different assumptions for the effectiveness of assessments and subsequent corrective actions to account for the differences between the two types of assessments. The Level 2 assessment is a more comprehensive investigation that may result in finding more substantial problems than what may be found during a Level 1 assessment, and for that reason the corrective actions that result from a Level 2 assessment were modeled to result in corrective action measures that are generally more expensive and have bigger and longer lasting effects than those of the Level 1 assessments. EPA conducted sensitivity analyses around the key assumptions summarized in Exhibit VI-2 as discussed in section VI.L of this preamble, *Uncertainties in the Benefit and Cost Estimate for the RTCR.*

2. Model used for PWSs serving > 4,100 people

For systems serving more than 4,100 people, EPA estimated violation and trigger rates using SDWIS/FED because the Six-Year Review 2 data for PWSs serving more than 4,100 people were not as robust as the Six-Year Review 2 data for systems serving 4,100 or fewer people. EPA did not quantify changes in violation or trigger rates for systems serving more than 4,100 people among the 1989 TCR, RTCR, and Alternative options because of: (1) limited Six-Year Review 2 data to characterize these systems, (2) the essentially unchanged monitoring requirements across options for these systems, and (3) the level of effort already occurring to implement the 1989 TCR.

D. Baseline Profiles

The estimate of baseline conditions that EPA developed provides a reference point for understanding net impacts of the RTCR.

Compliance with the GWR began in December 2009, and the expected compliance date of the RTCR is approximately six years following commencement of the GWR implementation.

The majority of PWSs are ground water systems and these systems are expected to be affected by the GWR. Because GWR implementation prior to the effective date of RTCR is expected to cause changes to ground water systems, the baseline conditions that EPA developed for ground water systems account for the expected effects of the GWR.

For PWSs serving more than 4,100 people, EPA assumed that present conditions, as reflected in 2005 SDWIS/FED data, are an appropriate representation of the conditions that are likely to exist when the RTCR becomes effective. EPA assumed that a steady state exists at the national level.

The number of ground water PWSs that disinfect is expected to change during implementation of the GWR before the expected rule compliance date of the RTCR. Exhibit VI-4 shows the estimated baseline number of the ground water PWSs at the RTCR compliance date.

Exhibit VI-4 Estimated Baseline Number of Ground Water Systems and Disinfection Status at compliance date (3 years post RTCR promulgation)

PWS Size	Number of Ground Water PWSs (Post-GWR)					
	CWS		NTNCWS		TNCWS	
	Disinfecting	Non-Disinfecting	Disinfecting	Non-Disinfecting	Disinfecting	Non-Disinfecting
≤100	6,190	5,748	2,938	5,888	13,753	46,447
101-500	9,311	4,581	2,776	3,837	5,451	13,824
501-1,000	3,512	955	873	845	684	1,279
1,001-4,100	5,422	1,021	547	265	274	343
4,101-33,000	2,798	358	56	14	27	40
33,001-96,000	307	28	2	-	-	2
96,001-500,000	62	1	-	-	-	1
500,001-1 M	4	-	-	-	-	1
>1 M	3	-	-	-	-	-
Total	27,610	12,691	7,191	10,850	20,189	61,937
Combined Total	40,301		18,041		82,126	

Source: RTCR Occurrence and Predictive Model Output as detailed in the RTCR EA (USEPA 2012a)

EPA estimated the numbers of ground water PWSs that monitor monthly, quarterly, and annually under the 1989 TCR based on an analysis of the Six-Year Review 2 data and individual State statutes conducted by EPA and the advisory committee Technical Work Group (TWG). Of the ground water PWSs serving 1,000 or fewer people, EPA estimated that approximately 34,000

monitor monthly, 67,000 monitor quarterly, and 27,000 monitor annually. EPA assumed that the numbers of systems on monthly, quarterly, and annual monitoring remain unchanged at the rule effective date for a continuation of the 1989 TCR. For the RTCR option, EPA assumed that only the percentage of systems that received an annual site visit under the 1989 TCR would continue on annual monitoring under the RTCR; the percentage of systems that would therefore no longer qualify for annual monitoring under the RTCR were assumed to revert to baseline quarterly monitoring. Under the Alternative option, all PWSs, regardless of size or type, start at monthly monitoring at the rule effective date.

The following two tables provide an overview of summary statistics relating to baseline water quality. Exhibit VI-5 shows the percentage of total coliform- and *E. coli*-positive samples based on PWS type and size. The percentages of samples that are total coliform-positive are generally higher in ground water systems than in surface water systems; in smaller systems than in larger systems; and in NCWSs than in CWSs.

Exhibit VI-5 Total Coliform and *E. coli* Percent Positive by System Size and Type

PWS Type	Source Water	Population Served	Total Coliform (# Samples)	Total Coliform (+ Samples)	Total Coliform (% Positive)	<i>E. coli</i> (# Samples) ¹	<i>E. coli</i> (+ Samples)	<i>E. coli</i> (% Positive) ²
CWS	Ground Water (GW)	≤100	93,105	2,479	2.66%	1,172	72	0.08%
		101 - 500	125,490	2,500	1.99%	1,639	61	0.05%
		501-1,000	48,265	736	1.52%	483	20	0.04%
		1,001-4,100	110,391	1,176	1.07%	732	21	0.02%
		4,101-33,000	183,721	877	0.48%	458	22	0.01%
		33,001-100,000	96,361	214	0.22%	44	2	0.00%
		>100,000	64,965	289	0.44%	34	1	0.00%
	Total GW	722,298	8,271	1.15%	4,562	199	0.03%	
	Surface Water (SW)	≤100	6,735	95	1.41%	64	6	0.09%
		101 - 500	19,716	227	1.15%	159	10	0.05%
		501-1,000	12,828	90	0.70%	70	7	0.05%
		1,001-4,100	55,310	314	0.57%	233	17	0.03%
		4,101-33,000	175,758	525	0.30%	399	41	0.02%
		33,001-100,000	112,894	157	0.14%	106	5	0.00%
>100,000		112,143	235	0.21%	99	2	0.00%	
Total SW	495,384	1,643	0.33%	1,130	88	0.02%		
GW & SW	Total CWS	1,217,682	9,914	0.81%	5,692	287	0.02%	
TNCWS	GW	≤100	163,730	7,820	4.78%	5,820	316	0.20%
		101 - 500	52,891	2,418	4.57%	1,869	99	0.19%
		501-1,000	6,952	299	4.30%	217	4	0.06%
		>1,000	7,062	143	2.02%	85	2	0.03%
	Total GW	230,635	10,680	4.63%	7,991	421	0.18%	
	SW	≤100	6,723	150	2.23%	141	17	0.25%
		101 - 500	2,854	75	2.63%	69	13	0.46%
501-1,000		523	19	3.63%	19	-	0.00%	

		>1,000	988	6	0.61%	37	-	0.00%
		Total SW	11,088	250	2.25%	266	30	0.27%
	GW & SW	Total TNCWS	241,723	10,930	4.52%	8,257	451	0.19%
NTNCWS	GW	≤100	46,505	1,476	3.17%	1,061	34	0.07%
		101 - 500	33,084	893	2.70%	628	19	0.06%
		501-1,000	9,531	166	1.74%	103	2	0.02%
		>1,000	13,138	177	1.35%	103	5	0.04%
		Total GW	102,258	2,712	2.65%	1,895	60	0.06%
	SW	≤100	1,668	32	1.92%	30	4	0.24%
		101 - 500	2,304	9	0.39%	9	2	0.09%
		501-1,000	932	6	0.64%	5	-	0.00%
		>1,000	1,316	1	0.08%	1	-	0.00%
		Total SW	6,220	48	0.77%	45	6	0.10%
GW & SW	Total NTNCWS	108,478	2,760	2.54%	1,940	66	0.06%	

¹ Number of samples that were specifically tested for *E. coli*. The denominator of the *E. coli* percent positive calculation includes this number plus the number of total coliform negative samples (number of total coliform samples – number of total coliform-positive samples).

² Percent of *E. coli*-positive was calculated as (number of *E. coli*-positive samples) / (number of *E. coli* samples taken) x 100.

Source: Derived using Six-Year Review 2 Data, which was filtered by including a State only if the State's PWSs as a group had submitted at least 50 percent of the expected sample-months of usable data. The *Total Coliform Compliance Monitoring Data Quality and Completion Report* (USEPA 2010b) includes a detailed description of this data cleaning process.

Exhibit VI-6 presents the number of acute and non-acute violations reported by PWSs. The number of violations is also an indicator of baseline water quality prior to implementation of the RTCR. As discussed in detail chapter 5 of the RTCR EA, EPA used these data to estimate the numbers of MCL violations and triggers for PWSs serving more than 4,100 people for the three options. Under the 1989 TCR, larger systems incur a relatively small number of violations annually, while smaller systems incur the majority.

Exhibit VI-6 Baseline Number of TCR Violations by System Size and Type (2005)

	Ground Water PWSs			Surface Water PWSs			All PWSs Total
	Non-Acute	Acute	Total	Non-Acute	Acute	Total	
CWSs							
<100	905	52	957	16	3	19	976
101-500	809	34	843	50	7	57	900
501-1,000	203	13	216	16	3	19	235
1,001-3,300	272	8	280	55	7	62	342
3,301-10,000	171	8	179	75	3	78	257
10,001-50,000	125	8	133	78	4	82	215
50,001-100,000	11	2	13	5	4	9	22
100,001-1M	1	1	2	4	1	5	7
> 1M	-	-	-	-	-	-	-
Total CWSs	2,497	126	2,623	299	32	331	2,954
NTNCWSs							
<100	514	34	548	7	2	9	557
101-500	346	20	366	4	-	4	370
501-1,000	57	6	63	2	-	2	65

1,001-3,300	58	4	62	-	-	-	62
3,301-10,000	9	2	11	1	-	1	12
10,001-50,000	1	-	1	-	-	-	1
50,001-100,000	-	-	-	-	-	-	-
100,001-1M	1	-	1	-	-	-	1
> 1M	-	-	-	-	-	-	-
Total NTNCWSs	985	66	1,051	14	2	16	1,067
TNCWSs							
<100	2,665	278	2,943	19	5	24	2,967
101-500	833	76	909	11	1	12	921
501-1,000	133	11	144	4	-	4	148
1,001-3,300	58	2	60	1	-	1	61
3,301-10,000	5	-	5	1	-	1	6
10,001-50,000	-	-	-	-	-	-	-
50,001-100,000	-	-	-	-	-	-	-
100,001-1M	-	-	-	-	-	-	-
> 1M	-	-	-	-	-	-	-
Total TNCWSs	3,694	367	4,061	36	6	42	4,103
Grand Total	7,176	559	7,735	349	40	389	8,124

Note: The RTCR EA uses violations data for PWSs serving greater than 4,100 people to estimate triggers for these systems. Data for other system sizes is provided for reference.

Source: Acute/Non-Acute Violations from SDWIS/FED annual data for period ending 3rd quarter 2001 – 2007 (only 2005 data is presented in this exhibit). OH, U.S. territories, Tribal PWS data excluded. See the RTCR EA (USEPA 2012a) for additional details.

E. Anticipated Benefits of the RTCR

In promulgating the RTCR, EPA expects to further reduce the risk of contamination of public drinking water supplies from the current baseline risk under the 1989 TCR. The options considered during development of this rule and analyzed as part of the RTCR EA are designed to achieve this reduction while maintaining public health protection in a cost-effective manner.

This section examines the benefits in terms of trade-offs among compliance with the 1989 TCR option, the RTCR option, and the Alternative option. Because there are insufficient data reporting the co-occurrence in a single sample of fecal indicator *E. coli* and pathogenic organisms and because the available fecal indicator *E. coli* data from the Six-Year Review 2 dataset were limited to presence-absence data, EPA was unable to quantify health benefits for the RTCR. EPA used several methods to qualitatively evaluate the benefits of the RTCR options. The qualitative evaluation uses both the judgment of EPA as informed by the TCRDSAC deliberations as well as quantitative estimates of changes in total coliform occurrence and counts

of systems implementing corrective actions. The evaluation characterizes, in relative terms, the reduction in risk for each regulatory scenario as compared to baseline conditions.

Since *E. coli* is an indicator of fecal contamination, EPA assumed that a decrease in *E. coli* occurrence in the distribution system would be associated with a decrease in fecal contamination in the distribution system. In general, this decrease in fecal contamination should reduce the potential risk to human health for PWS customers. Thus, any reduction in *E. coli* occurrence is considered a benefit of the RTCR. Since fecal contamination may contain waterborne pathogens including bacteria, viruses, and parasitic protozoa, in general, a reduction in fecal contamination should reduce the risk from all of these contaminants.

As presented in Exhibit VI-5, the percentages of samples that are positive for total coliforms and *E. coli* are generally higher for PWSs serving 4,100 or fewer people than those serving more than 4,100 people. PWSs with higher total coliform and *E. coli* occurrence are more likely to be triggered into assessments and corrective action. As discussed previously, the assessments and corrective action lead to a decrease in total coliform and *E. coli* occurrence. Because the PWSs serving 4,100 or fewer people have a higher initial *E. coli* occurrence and are likely triggered into more assessments and corrective actions than larger PWSs, the increase in benefits for these small systems are likely more evident as compared to the larger systems. In particular, model results suggest that customers of small ground water TNCWSs serving 100 or fewer people, which constitute approximately 40 percent of PWSs, experience the most improvement in water quality under the RTCR. That is, the occurrence of *E. coli* is predicted to decrease more for these systems than for other systems types.

1. Relative risk analysis

When revising an existing drinking water regulation, one of the main concerns is to ensure that backsliding on water quality and public health protection does not occur. SDWA requires that EPA maintain or improve public health protection for any rule revision. The RTCR is more stringent than the 1989 TCR with regard to protecting public health. The basis for this perspective is provided in this subsection and the following subsections (sections VI.E.2, *Changes in violation rates and corrective actions*, and VI.E.3, *Nonquantifiable benefits*) of this preamble.

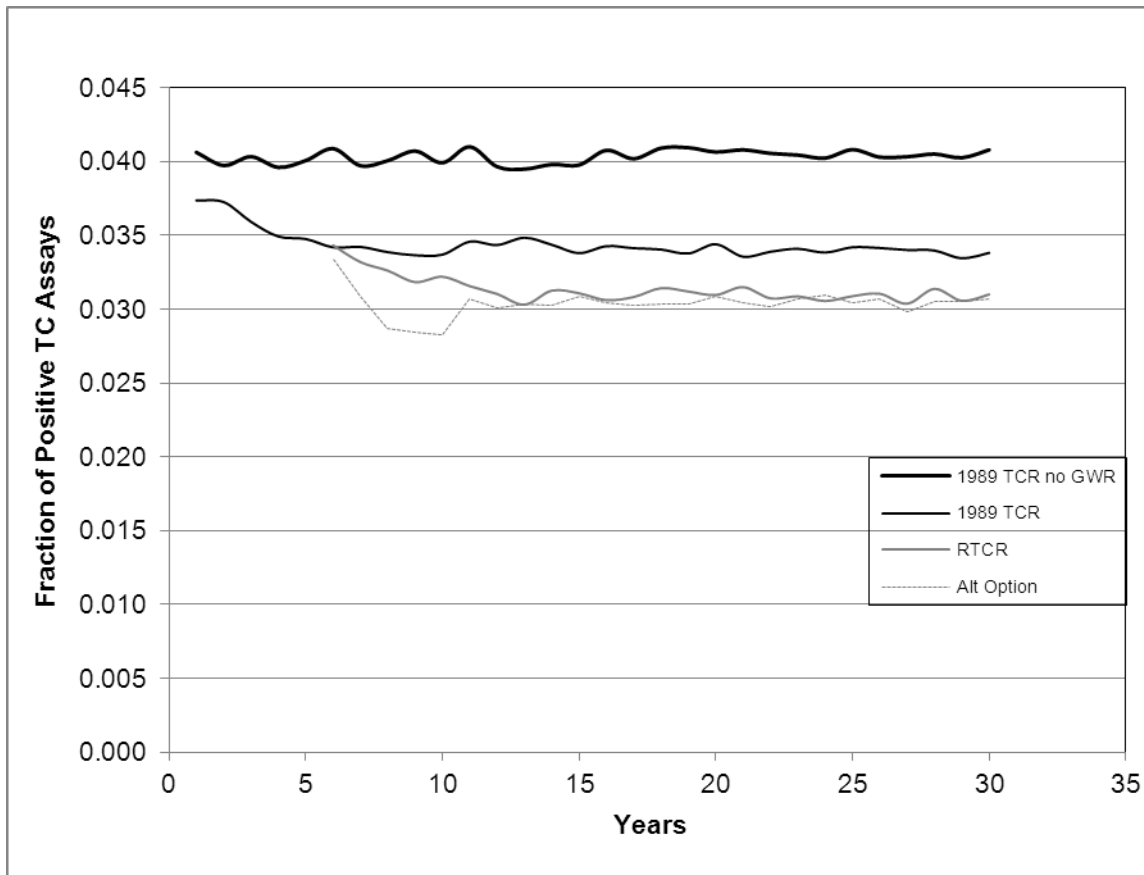
Risk reduction for the RTCR is characterized by the activities performed that are presumed to reduce risk of exposing the public to contaminated water. These activities are considered under each rule component presented in Exhibit VI-8.

More frequent monitoring has the potential to decrease the risk of contamination in PWSs based on an enhanced ability to diagnose and mitigate system issues in a more timely fashion. Conversely, less frequent monitoring has the potential to increase risk. Real-time continuous sampling would mitigate the most risk possible based on sampling schedule; however, it would cost prohibitively more than the periodic sampling practiced under the 1989 TCR and included in the RTCR and the Alternative option. EPA's objective in proposing the sampling schedules included in the RTCR and Alternative option was to find an appropriate balance between the factors of risk mitigation and cost management.

Under the RTCR and Alternative option, the reduction in the number of required repeat samples and additional routine samples for some PWSs has the potential to contribute to increased risk for PWS customers (see also section III.C, *Monitoring*, and III.D, *Repeat Samples*, of this preamble for discussions on the additional routine sample and repeat sample provisions respectively). However, this potential increase in risk is expected to be more than offset by

potential decreases in risk from increased routine monitoring (see section III.C of this preamble, *Monitoring*) and the addition of the assessments and corrective action provisions (see section III.E of this preamble, *Coliform Treatment Technique*) that find and fix problems indicated by monitoring. Exhibit VI-7 illustrates the predicted reduced frequency at which total coliforms occur subsequent to the implementation of the RTCR and Alternative option. As discussed previously, the RTCR uses total coliform occurrence as an indicator of potential pathways for possible contamination to enter the distribution system (see section III.B of this preamble, *Rule Construct: MCLG and MCL for E. coli and Coliform Treatment Technique*). Exhibit VI-7 illustrates the combined effects on total coliform occurrence resulting from changes in monitoring and the effects of assessments and corrective actions for the different rule options for very small systems. The relative trends indicated in Exhibit VI-7 for TNCWSs also pertain to other PWS categories as illustrated in chapter 5 of the RTCR EA. EPA chose to include the characterization for TNCWSs because they represent the system category of largest influence on the national impacts.

Exhibit VI-7 Ground Water Transient Non-community Water System (Summary of Systems Serving $\leq 4,100$) Total Coliform Occurrence



Source: RTCR occurrence model as described in the RTCR EA (USEPA 2012a).

The effect that the elimination of public notification requirements for monthly/non-acute MCL violations has on risk is difficult to predict. Some factors, such as reduction in available public information and possible PWS complacency, lead to a potential increase in risk and other factors, such as less confusion (PN more in line with potential health risks) and PWSs resources used more efficiently, lead to a potential decrease, as discussed in Exhibit VI-8. This change to PN is addressing a key concern expressed by various stakeholders in the advisory committee and during the Six-Year Review 1 comment solicitation process. By eliminating the requirement and replacing it with assessment and corrective action requirements, the Agency expects less public

confusion, more effective use of resources, increased transparency, and increased public health protection.

Other rule components are expected to have a negligible effect on risk. However, the overall effect of the RTCR is expected to be a further reduction in risk from the current baseline risk under the 1989 TCR. Chapter 6 of the RTCR EA presents a detailed discussion of the potential influence on health risk for each rule component.

Exhibit VI-8 Potential Changes in Risk under the RTCR and Alternative Option Relative to the 1989 TCR

RTCR Component	Factors Leading to a Potential Increase in Risk		Factors Leading to a Potential Decrease in Risk		Overall Predicted Change in Risk	
	RTCR	Alternative	RTCR	Alternative	RTCR	Alternative
Implementation Activities	None	None	None	None	No change	No change
Routine Monitoring (Including Reduced Monitoring)	None	None	Increased stringency in requirements to qualify for reduced monitoring along with requirement to return to baseline monitoring upon loss of these criteria is expected to result in decreased risk (That is, fewer PWSs will qualify and therefore PWSs will on average monitor more frequently than under the baseline for reduced monitoring)	PWSs all monitor monthly in the first few years of implementation of the RTCR, which is an increase in sampling frequency for systems that monitor quarterly or annually under the 1989 TCR. After the first few years, systems may reduce to quarterly, but none may reduce to annual monitoring, creating a decrease in risk for systems on annual monitoring under the 1989 TCR	Decrease	Decrease
Repeat Monitoring	Required repeat samples reduced from 4 to 3 for systems serving <1,000 people	Same as RTCR option	None	None	Increase	Increase

Additional Routine Monitoring	Additional routine samples are no longer required for PWSs monitoring monthly. Ground water PWSs serving 1,000 or fewer people reduce additional routine samples from 5 to 3.	Same as RTCR option	None	None	Increase	Increase
Annual Site Visits	None (only States currently performing annual site visits are expected to continue).	Annual monitoring is not permitted under the Alternative option, so the protective benefit of the annual site visit is lost.	None	None	No change	Increase
Assessments	None	None	Mandatory assessments are a new requirement	Same as RTCR option	Decrease	Decrease
Corrective Actions	None	None	Mandatory corrective actions are a new requirement	Same as RTCR option	Decrease	Decrease
Public Notification – Monthly/Non-Acute MCL Violations	Reduction in available public information Possible PWS complacency	Same as RTCR option	Less confusion (PN more in line with potential health risks) PWSs resources used more efficiently	Same as RTCR option	Unknown	Unknown
Public Notification – Monitoring and Reporting Violations	None	None	Increased stringency of PNs motivates PWSs to conduct required sampling	Same as RTCR option	Decrease	Decrease
Overall					Decrease	Decrease

Notes: Detailed discussion of the rationale for determinations of potential risk for each rule component is presented in chapter 6 (section 6.2) of the RTCR EA (USEPA 2012a). Implementation activities consist of administrative activities by PWSs and States to implement the rule.

Assessment of potential changes in risk for monitoring components is an *overall* assessment. Potential changes (or static state) of risk for particular system sizes and types differ according to individual regulatory requirements and are discussed in section 6.2 of the RTCR EA. Chapter 3 of the RTCR EA provides a detailed description of the regulatory components for all three regulatory scenarios, and this preamble provides additional discussion of the TCRDSAC process and the rationale underlying the structure of the regulatory options considered.

2. Changes in violation rates and corrective actions

The quantified portion of the benefits analysis focuses on several measures that contribute to the changes in risk expected under the RTCR. Specifically, EPA modeled the predicted outcomes based on each regulatory option considered – baseline (1989 TCR), the RTCR (final

rule), and the Alternative option – in the form of estimates of non-acute violations for the 1989 TCR and assessment triggers for the RTCR and Alternative option; *E. coli* violations; and the number of corrective actions implemented under each option. This section of the preamble includes six graphs (Exhibit VI-9 through Exhibit VI-14) that help to illustrate these endpoints.

Evaluation of each of these endpoints informed EPA's understanding of potential changes to the underlying quality of drinking water. In particular, the number of corrective actions performed has a strong relationship to potential improvements in water quality and public health. For a given rate of total coliform and *E. coli* occurrence, an increase in the number of corrective actions implemented leads to improved water quality. However, a reduction in sampling likely leads to a reduction in total coliform and *E. coli* positives being found, which in turn likely leads to a reduction in assessments and corrective actions being implemented. The number of total coliform and *E. coli* positives that are prevented, missed, or found under each regulatory option considered in comparison to those predicted under the 1989 TCR results in estimates of annual non-acute and acute violations (1989 TCR) and assessment triggers (RTCR and Alternative option). Section 6.4 of the RTCR EA presents a step-wise sensitivity analysis of the competing effects of additional protective activity (e.g., assessments and corrective actions) and decreased additional routine and repeat sampling of the RTCR compared to the 1989 TCR. The conclusions of this sensitivity analysis showed that for all categories of systems, more total coliform and *E. coli* positives are expected to be prevented than missed under the RTCR relative to the 1989 TCR.

For each of the graphs presented in Exhibit VI-9 through Exhibit VI-14, there are two main model drivers that affect the endpoints depicted: the total number of samples taken over time (including routine, additional routine, and repeat samples) and the effect of corrective actions

taken. When looking at the comparisons between the 1989 TCR with the RTCR across all PWSs, the overall effect of the total numbers of samples taken is negligible because the total number of samples predicted to be taken throughout the period of analysis is almost the same (approximately 82M samples) under both the 1989 TCR and RTCR. For the Alternative option, the analysis predicts that approximately 88M total samples are taken over the period of analysis. Exhibit VI-18 of this preamble presents estimated total numbers of samples taken over the 25-year period of analysis. Based on the relationships of total samples taken among the 1989 TCR, RTCR, and Alternative option, the best way to interpret the graphs presented in this section is in a step-wise manner.

The first comparison that should be made is between the 1989 TCR option and RTCR. Because similar total numbers of samples are taken under the 1989 TCR and RTCR, the major effect seen in the graphs can be isolated to the effects that implementation of corrective actions has on underlying occurrence and how that occurrence influences the endpoint in question (assessments, *E. coli* MCL violations, and corrective actions). In each graph, this is depicted by a marked reduction in the endpoint under the RTCR compared to the 1989 TCR option and is a reflection of overall better water quality. The second comparison can then be made of the Alternative option against the RTCR. In each graph, the predicted results (assessments, *E. coli* MCL violations, and corrective actions) for the Alternative option are above those for the RTCR and represent an additional benefit over the RTCR. This additional benefit is primarily a function of the additional diagnostic abilities gained through increased monitoring under the Alternative option, and is especially prominent in the early years of the analysis, since all systems are initially required to monitor at least monthly.

More detailed descriptions of each endpoint considered in terms of the evaluation process described previously are provided in this section as they apply to the individual graphs in Exhibit VI-9 through VI-14. Each of the graphs shown in this section is presented first in nondiscounted terms, and then based on a discount rate of three percent to reflect the reduced valuation of potential benefits over time, consistent with the presentation of costs in the section that follows. Graphs of benefits discounted using seven percent discounted rates are presented in Appendix B of the RTCR EA.

Exhibit VI-9 shows the effect (on average across all PWSs) of the RTCR and the Alternative option on the annual number of non-acute violations (1989 TCR) and assessment triggers (RTCR and Alternative option) over time. The estimated reduction of annual assessment triggers (from the 1989 TCR estimates of non-acute violations) by approximately 1,000 events under the RTCR is a reflection of the improved water quality expected under the RTCR. A similar but smaller reduction in non-acute violations (Level 1 triggers) from the 1989 TCR is seen under the Alternative option. The larger initial estimate of assessment triggers followed by a higher steady state number for the Alternative option than seen under the RTCR reflects the diagnostic abilities provided by increased sampling under the Alternative option. The additional triggers identified by increased sampling under the Alternative option translate into greater potential benefits than under the RTCR.

Exhibit VI-10 shows the effect (on average across all PWSs) of the RTCR and the Alternative option with respect to *E. coli* violations found over the 25-year period of analysis in comparison to the 1989 TCR. The overall reduction in annual *E. coli* violations under the RTCR of more than 100 events is a measure that should correlate more closely with expected benefits (that is, reductions in adverse health outcomes) than non-acute events (as presented in Exhibit

VI-9) because *E. coli* violations are a direct result of measurement of fecal contamination in water. A similar but smaller reduction in *E. coli* violations is seen under the Alternative option after steady state is achieved. This is the result of two off-setting effects. The “true” number of steady state violations under the Alternative option is lower because there is a greater likelihood that violations will be found and fixed. However, the additional monitoring leads to a higher percentage of violations being detected. This second effect outweighs the first, so that the total number of detected violations in the steady state is higher than for the RTCR, even though the underlying “true” number of violations is lower. This lower number of “true” violations means that the Alternative option is more protective of public health, even though more violations are detected.

Exhibit VI-11 presents estimates over the 25-year period of analysis of the increase in corrective actions relative to the 1989 TCR (on average across all PWSs) attributable to the RTCR and Alternative option. Performance of these additional corrective actions is expected to result in the most direct benefits under the RTCR. Because only the incremental numbers of corrective actions estimated under the RTCR and Alternative option were modeled, the reference point for comparison to the 1989 TCR is the base (zero) line in the graph. The RTCR EA assumes that corrective actions are already being performed under the 1989 TCR. Baseline corrective actions are taken into account by assuming only a modest incremental increase of 10 percent in implementation of effective corrective actions under both the RTCR and Alternative option.

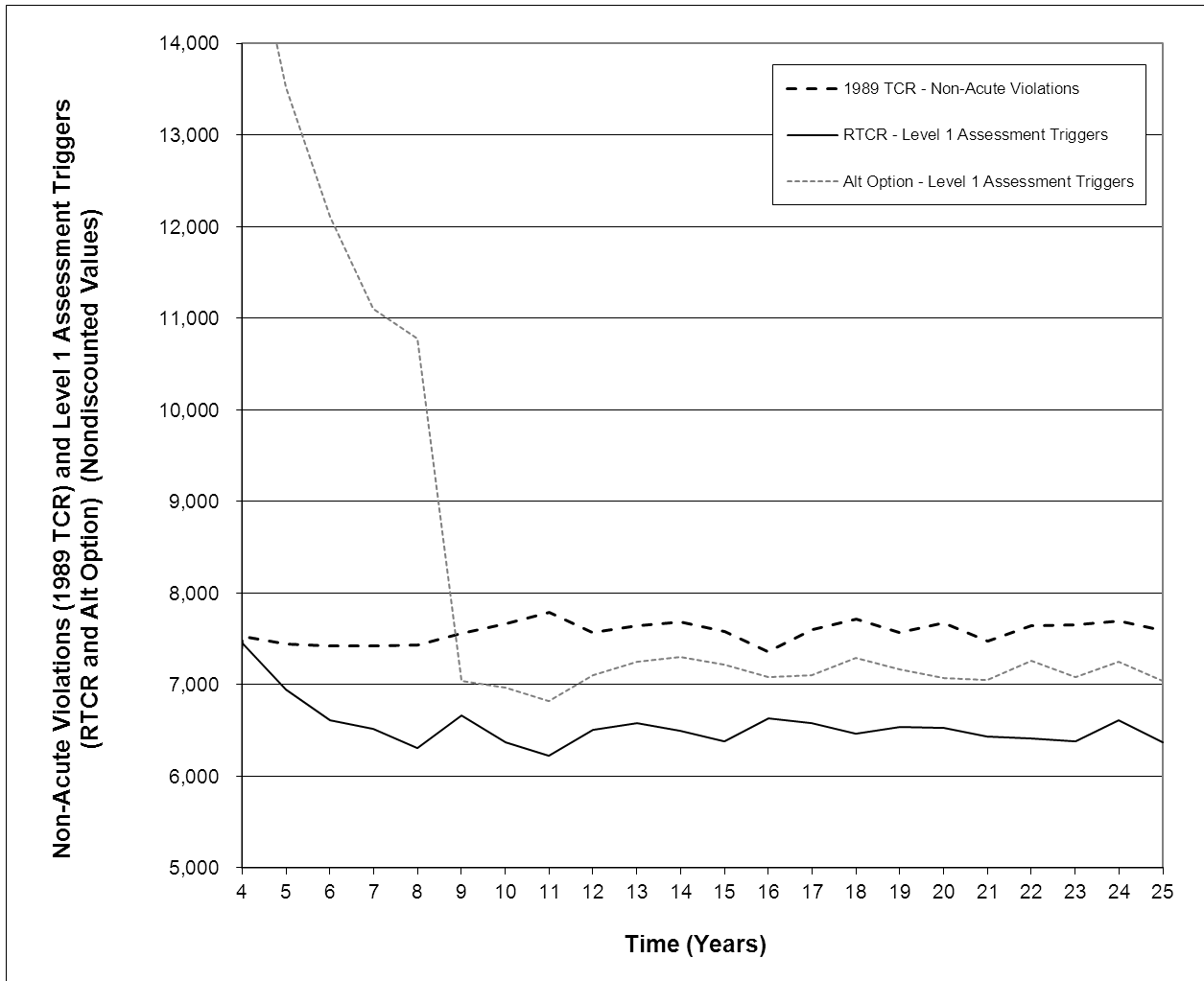
Exhibit VI-11 indicates that more corrective actions are implemented under the Alternative option than under the RTCR. This is driven, again, by the increased diagnostic power of more sampling and reflects additional potential benefits beyond those gained under the RTCR.

Taken together, Exhibit VI-9 through Exhibit VI-11 indicate that the modeled endpoints for the RTCR and the Alternative option predict positive benefits in comparison to the 1989 TCR; in particular, the Alternative option captures more benefits than the RTCR. Similar to the patterns seen in Exhibits VI-9 through VI-11, for each of the discounted endpoints presented over time in Exhibits VI-12 through VI-14, the graphs show that (on average across all PWSs) the Alternative option provides more benefit than the RTCR, and both provide more benefit than the 1989 TCR. These outcomes are consistent with the qualitative assessment of the benefits summarized in this section of this preamble.

The major difference between the RTCR and the Alternative option is the increased monitoring that is required under the Alternative option. The increased diagnostic ability of the extra samples taken under the Alternative option is seen in the large difference in the endpoint counts through the first several years in Exhibit VI-9 through Exhibit VI-14. Absent this effect, the Alternative option essentially mirrors the RTCR in the exhibits. Even though the predicted results (assessments, *E. coli* MCL violations, and corrective actions) under the Alternative option are greater than the 1989 TCR at first, the trend is due to initially finding more problems through monitoring. The increased monitoring during the first several years under the Alternative option results in a frontloading of benefits at the beginning of the implementation period. The benefits, however, tend to even out over time between the RTCR and Alternative option as eligible systems qualify for less intense (quarterly) monitoring under the Alternative option. However, the Alternative option leads to a greater number of assessments, *E. coli* MCL violations, and corrective actions than the RTCR because all PWSs are required to sample no less than quarterly under the Alternative option while under the RTCR qualifying PWSs are permitted to sample at

a minimum of once per year: more monitoring has the potential for more triggered assessments, corrective actions, and/or violations than less monitoring.

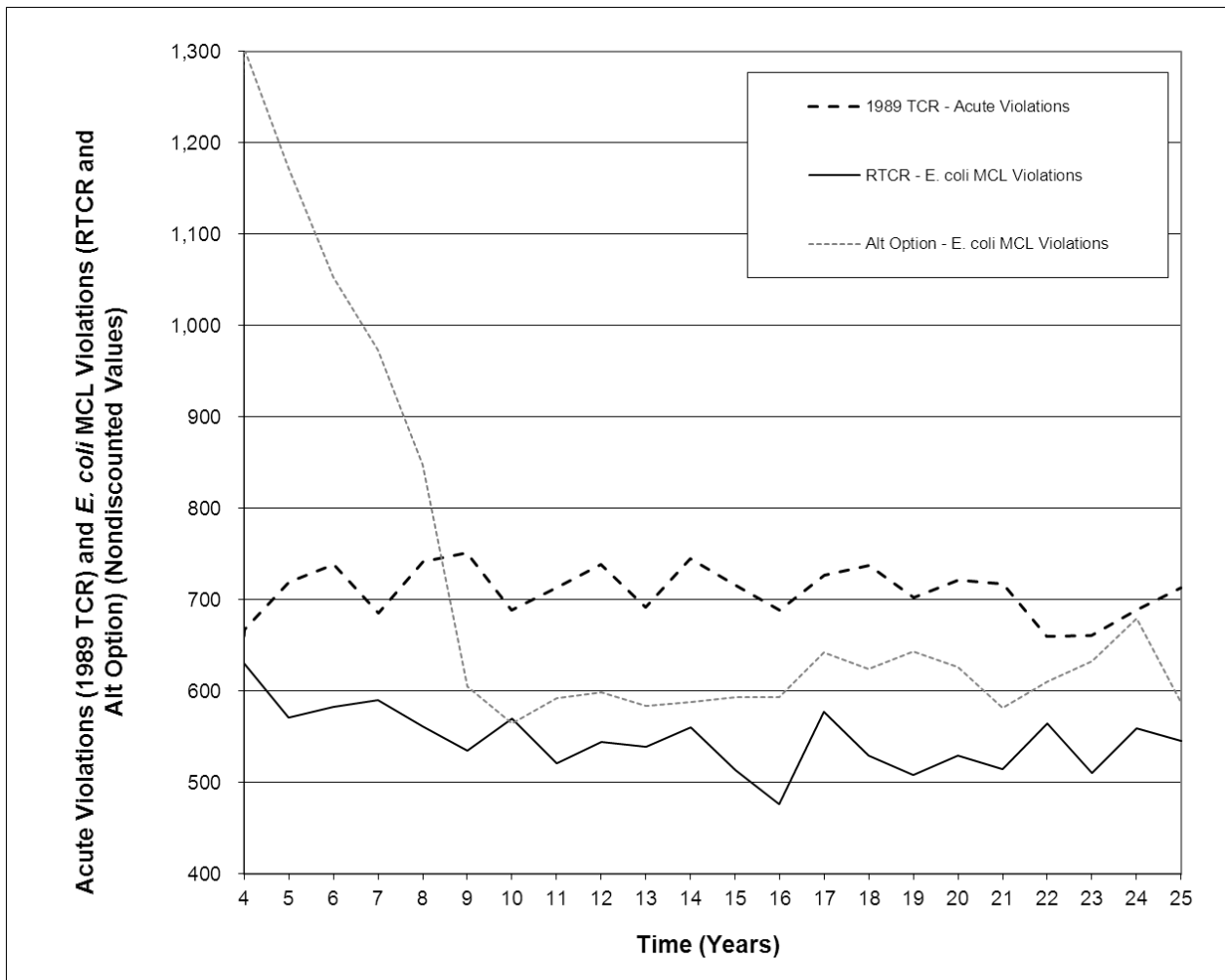
Exhibit VI-9 Estimates of Non-Acute Violations (1989 TCR) and Level 1 Assessment Triggers (RTCR and Alternative Option)



Notes: X-axis begins at Year 4 after rule promulgation, which is the first year of full implementation of the RTCR and Alternative option. The annual rates of non-acute violations (1989 TCR) and Level 1 assessment triggers (RTCR and Alternative option) as predicted by the model reach a steady state beginning in approximately Year 9, by which time PWSs that are expected to meet the criteria for reduced monitoring begin reduced monitoring, and the distribution of PWSs that monitor monthly, quarterly, and annually is assumed to remain relatively constant. Estimates represent the annual number of assessment triggers found by each option and the non-acute violations found under the 1989 TCR.

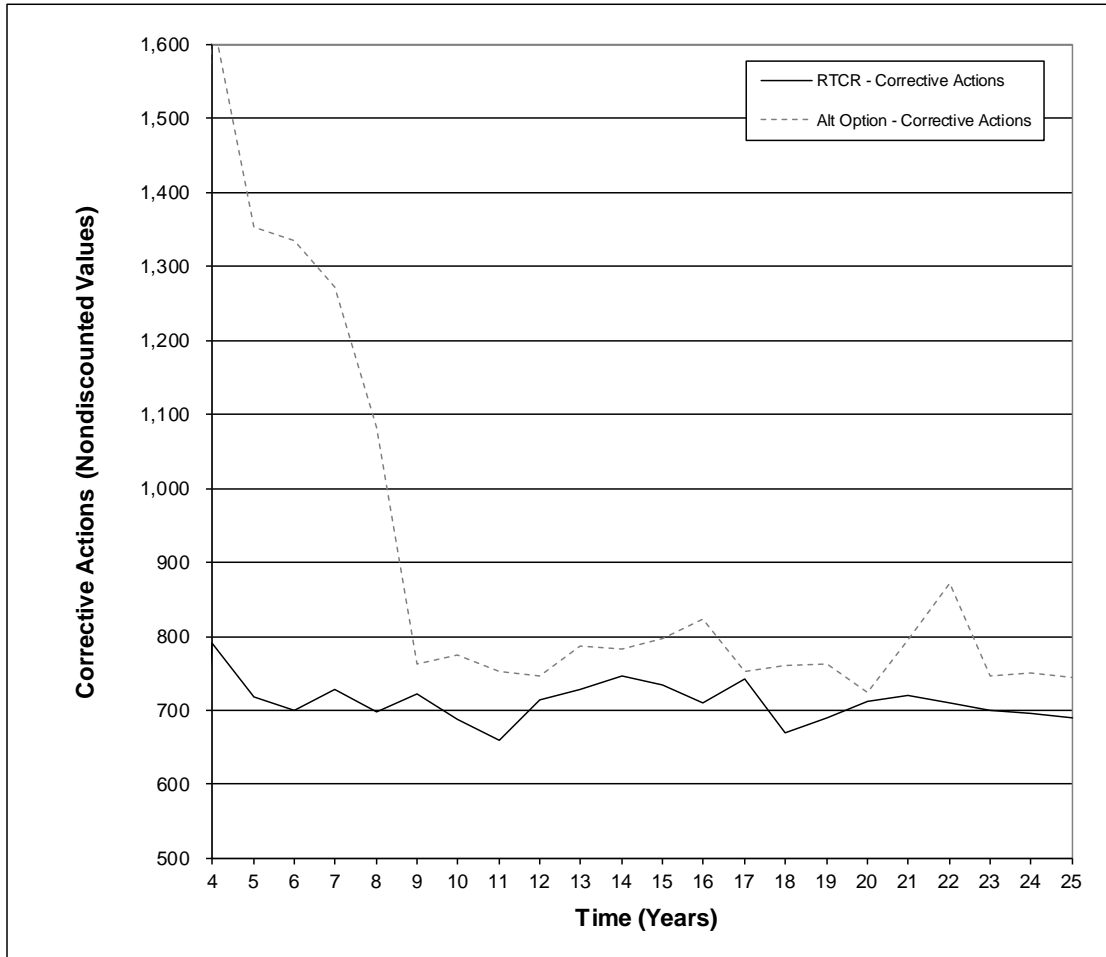
Source: RTCR occurrence model output.

Exhibit VI-10 Estimates of Acute Violations (1989 TCR) and *E. coli* MCL Violations (RTCR and Alternative Option)



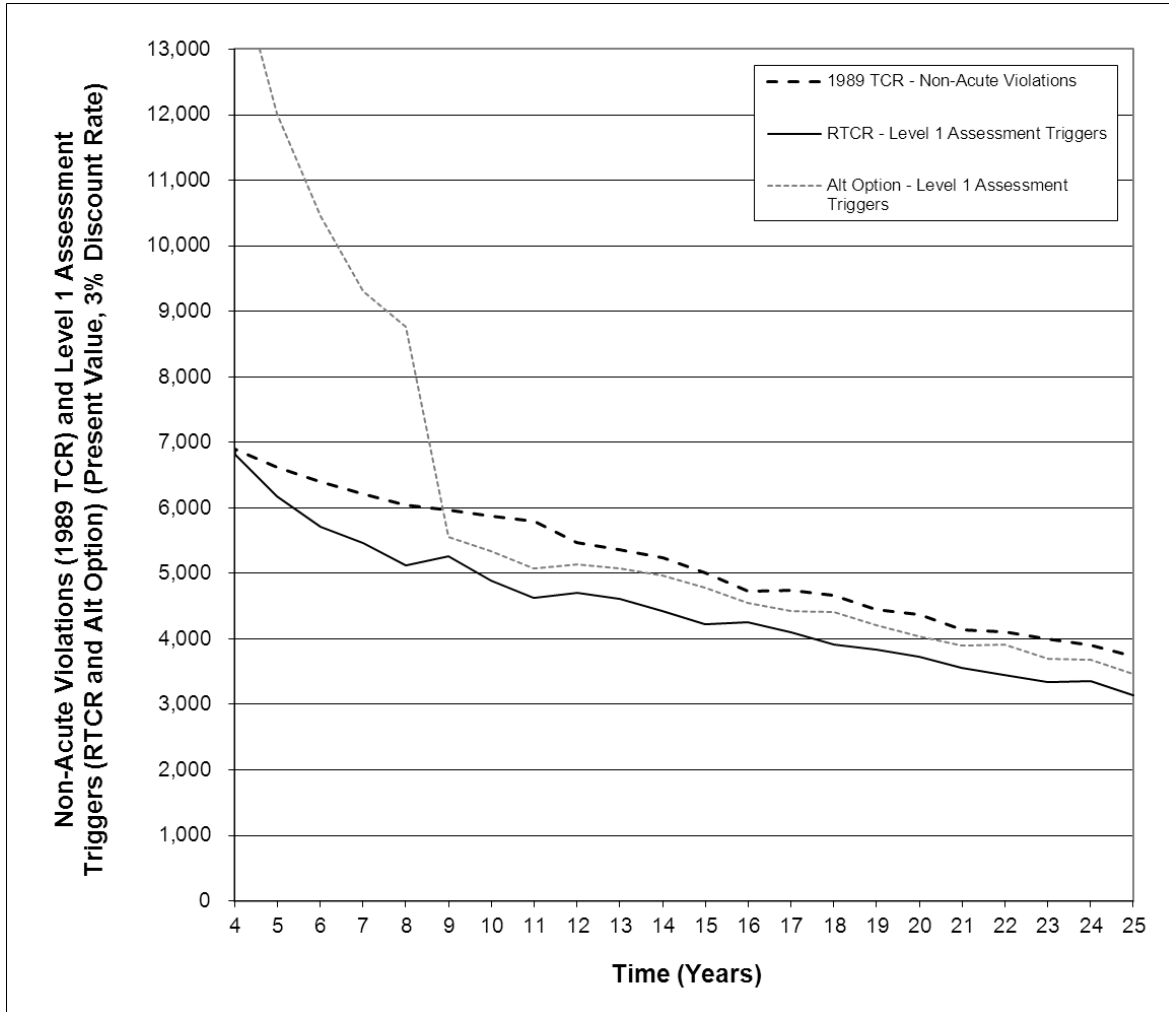
Notes: X-axis begins at Year 4 after rule promulgation, which is the first year of full implementation of the RTCR and Alternative option. The annual rates of acute violations (1989 TCR) and *E. coli* MCL violations (RTCR and Alternative option) as predicted by the model reach steady state in approximately Year 9, by which time PWSs that are expected to meet the criteria for reduced monitoring begin reduced monitoring, and the distribution of PWSs that monitor monthly, quarterly, and annually is assumed to remain relatively constant. Estimates represent the annual number of acute violations found by each option and the 1989 TCR.
 Source: RTCR occurrence model output.

Exhibit VI-11 Estimates of Corrective Actions



Notes: X-axis begins at Year 4 after rule promulgation, which is the first year of full implementation of the RTCR and Alternative option. The annual rates of corrective actions as predicted by the model reach a steady state beginning approximately in Year 9, by which time PWSs that are expected to meet the criteria for reduced monitoring begin reduced monitoring, and the distribution of PWSs that monitor monthly, quarterly, and annually is assumed to remain relatively constant. All corrective actions performed are in addition to activity under the 1989 TCR, which does not require corrective actions. Therefore the 1989 TCR is not included in this graph.
 Source: RTCR occurrence model output.

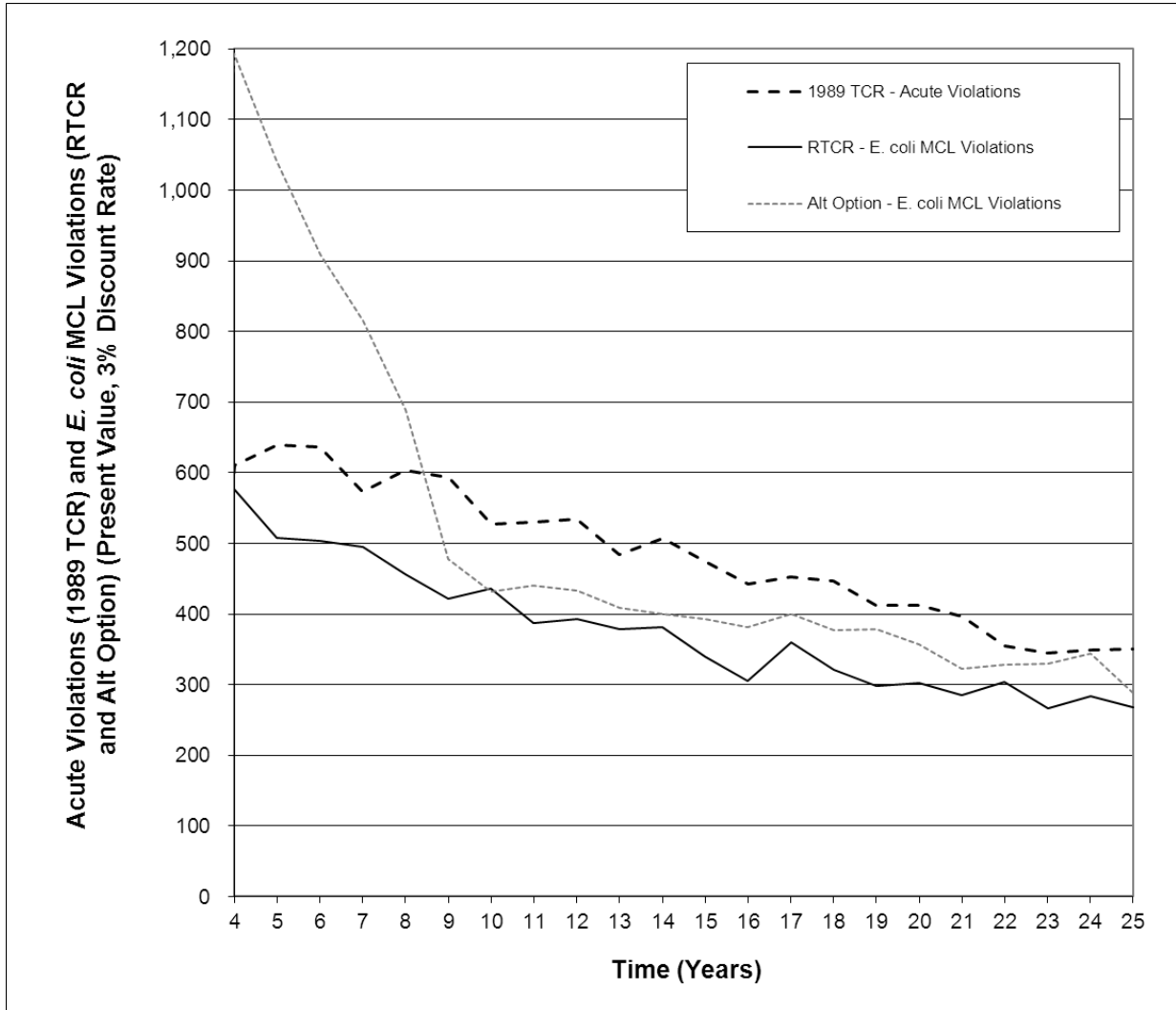
Exhibit VI-12 Discounted Estimates of Non-Acute Violations (1989 TCR) and Level 1 Assessment Triggers (RTCR and Alternative Option) (three percent discount rate)



Notes: X-axis begins at Year 4 after rule promulgation, which is the first year of full implementation of the RTCR and Alternative option. The annual rates of non-acute violations (1989 TCR) and Level 1 assessment triggers (RTCR and Alternative option) as predicted by the model reach a steady state beginning in approximately Year 9, by which time PWSs that are expected to meet the criteria for reduced monitoring begin reduced monitoring, and the distribution of PWSs that monitor monthly, quarterly, and annually is assumed to remain relatively constant. Estimates represent the annual number of assessment triggers found by each option and the non-acute violations found under the 1989 TCR.

Source: RTCR occurrence model output.

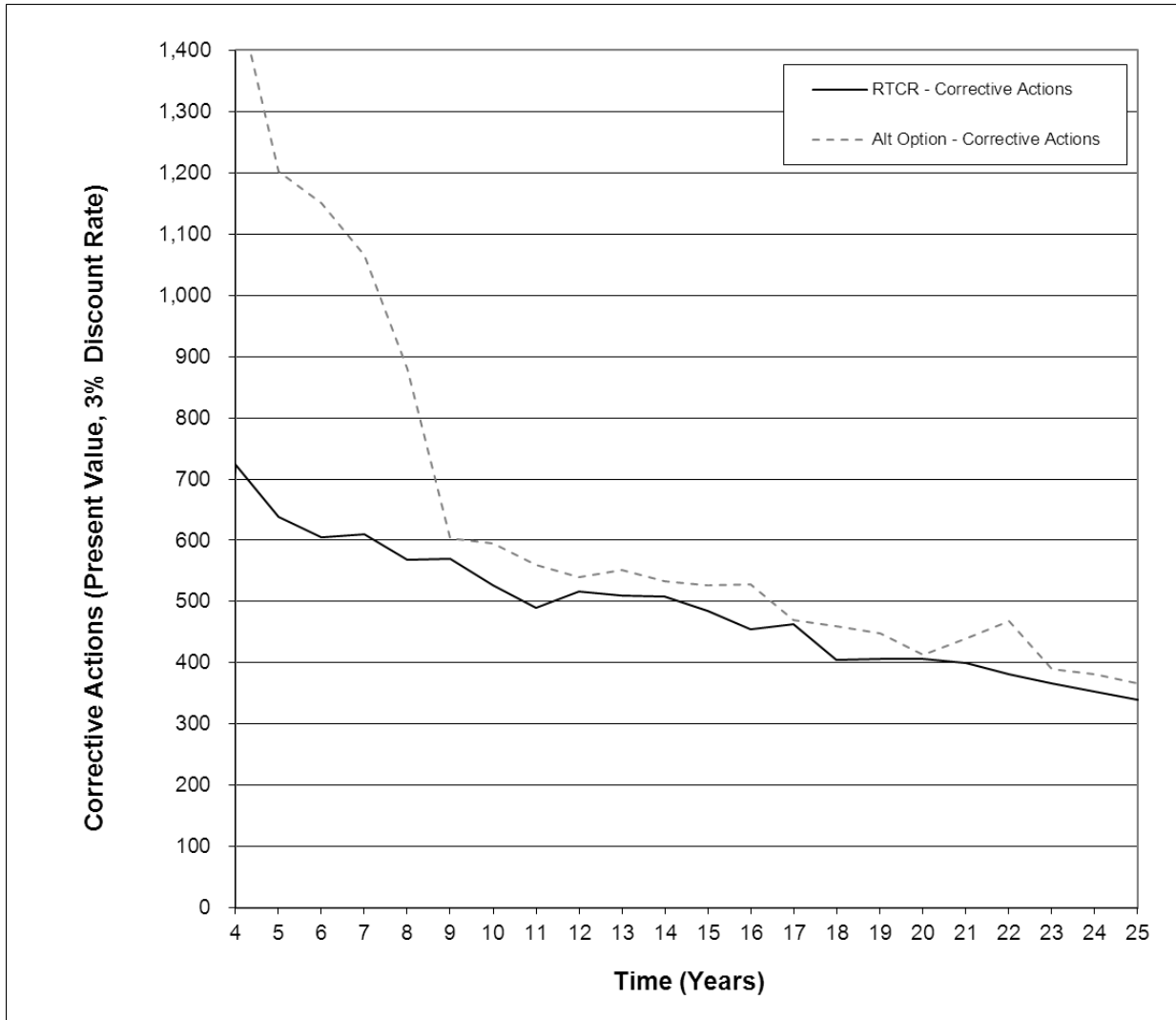
Exhibit VI-13 Discounted Estimates of Acute Violations (1989 TCR) and *E. coli* Violations (RTCR and Alternative Option) (three percent discount rate)



Notes: X-axis begins at Year 4 after rule promulgation, which is the first year of full implementation of the RTCR and Alternative option. The annual rates of acute violations (1989 TCR) and *E. coli* MCL violations (RTCR and Alternative option) as predicted by the model reach steady state in approximately Year 9, by which time PWSs that are expected to meet the criteria for reduced monitoring begin reduced monitoring, and the distribution of PWSs that monitor monthly, quarterly, and annually is assumed to remain relatively constant. Estimates represent the annual number of acute violations found by each option and the 1989 TCR.

Source: RTCR occurrence model output.

Exhibit VI-14 Discounted Estimates of Corrective Actions (three percent discount rate)



Notes: X-axis begins at Year 4 after rule promulgation, which is the first year of full implementation of the RTCR and or Alternative option. The annual rates of corrective actions as predicted by the model reach a steady state beginning in approximately Year 9, by which time PWSs that are expected to meet the criteria for reduced monitoring begin reduced monitoring, and the distribution of PWSs that monitor monthly, quarterly, and annually is assumed to remain relatively constant. All corrective actions performed are in addition to activity under the 1989 TCR, which does not require corrective actions. Therefore the 1989 TCR is not included in this graph. Source: RTCR occurrence model output.

3. Nonquantifiable benefits

a. *Potential decreased incidence of endemic illness from fecal contamination, waterborne pathogens, and associated outbreaks.* As discussed in section VI.E of this preamble, *Anticipated Benefits of the RTCR*, and chapter 2 of the RTCR EA, benefits from the RTCR may include

avoidance of a full range of health effects from the consumption of fecally contaminated drinking water, including the following: acute and chronic illness, endemic and epidemic disease, waterborne disease outbreaks, and death. EPA recognizes that the EPA-approved standard methods available for *E. coli* do not typically identify the presence of the pathogenic *E. coli* strains, such as *E. coli* O157:H7. Thus, *E. coli* occurrence, as used in this EA, serves as an indication of fecal contamination but not necessarily pathogenic contamination. See also discussion in section II.D of this preamble, *Public Health Concerns Addressed by the Revised Total Coliform Rule*.

EPA was unable to quantify the cases of morbidity or mortality avoided because there are insufficient data reporting the co-occurrence of fecal indicator *E. coli* and pathogenic organisms in a single water sample, and because the available fecal indicator *E. coli* data from the Six-Year Review 2 dataset were limited to presence-absence data. Instead, EPA estimated changes in total coliform and fecal indicator *E. coli* occurrence and changes in number of corrective actions as measures of reduced risk. As discussed previously, the assessments and corrective actions required under the RTCR will help lead to a decrease in total coliform and *E. coli* occurrence in drinking water. Since fecal contamination can contain waterborne pathogens including bacteria, viruses, and parasitic protozoa, in general, a reduction in fecal contamination should reduce the potential risk from all of these contaminants and the associated primary and secondary endemic disease burden, both acute and chronic.

b. Other nonquantifiable benefits. This section describes other nonquantified benefits, which include those associated with increased knowledge regarding system operation, accelerated maintenance and repair, avoided costs of outbreaks, and reductions in averting behavior.

By requiring PWSs to conduct assessments that meet minimum elements focused on identifying sanitary defects in response to triggers for total coliform- or *E. coli*-positive samples, the RTCR increases the likelihood that PWS operators, in particular those of systems triggered to conduct assessments and corrective action, will develop further understanding of system operations and improve and practice preventive maintenance compared to the 1989 TCR, which does not require PWSs to perform assessments and corrective action.

Another non-quantified benefit is that systems may choose corrective actions that also address other drinking water contaminants. For example, correcting for a pathway of potential contamination into the distribution system can possibly also mitigate a variety of other potential contaminants. Due to the lack of data available on the effect of corrective action on contamination entering through distribution system pathways, EPA has not quantified such potential benefits.

Some systems may see additional nonquantified benefits associated with the acceleration of their capital replacement fund investments in response to early identification of impending problems with large capital components. Although such capital investment will eventually occur in the absence of RTCR requirements, earlier investment may ensure that problems are addressed in a preventive manner and may preclude some decrease in protection that might have occurred otherwise. At the very least, the increased operator awareness is expected to reduce the occurrence of unplanned capital expenditures in any given year. However, because of the difficulty of projecting when capital replacements would occur, EPA has not costed this acceleration of capital replacement, so there would also be a nonquantified cost of making such investments sooner.

Another major non-health benefit is the avoided costs associated with outbreak response. Outbreaks can be very costly for both the PWS and the community in which they occur. Avoided outbreak response costs include such costs as issuing public health warnings, boiling drinking water and providing alternative supplies, remediation and repair, and testing and laboratory costs. Reduced total coliform occurrence resulting from the RTCR may also lead to a reduction of costs associated with boil-water orders, which some States require following non-acute violations under the 1989 TCR. Taken together, these expenses can be quite significant. For example, an analysis of the economic impacts of a waterborne disease outbreak in Walkerton, Ontario (population 5,000) estimated the economic impact (excluding estimates of the value of a statistical life for seven deaths and intangible costs for illness-related suffering) to be over \$45.9M in 2007 Canadian dollars (approximately \$42.8M 2007 US dollars) (Livernois 2002). Note that some of these costs were incurred by individuals and businesses in neighboring communities. The author of the study suggested that this was a conservative estimate.

In addition, the RTCR may also reduce uncertainty regarding drinking water safety, which may lead to reduced costs for averting behaviors. Averting behaviors include the use of bottled water and point-of-use devices. This benefit also includes the reductions in time spent on averting behavior such as the time spent obtaining alternative water supplies.

F. Anticipated Costs of the RTCR

To understand the net impacts of the RTCR on public water systems and States in terms of costs, EPA first used available data, information, and best professional judgment to characterize how PWSs and States are currently implementing the 1989 TCR. Then, EPA considered the net change in costs that results from implementing the RTCR or Alternative option as compared to the costs of continuing with the 1989 TCR. The objective was to present the net change in costs

resulting from revisions to the 1989 TCR rather than absolute total costs of implementing the 1989 TCR as revised by the RTCR. More detailed information on cost estimates is provided in the sections that follow and a complete discussion can be found in chapter 7 of the RTCR EA. A detailed discussion of the RTCR requirements is located in section III of this preamble,

Requirements of the Revised Total Coliform Rule.

1. Total annualized present value costs

To compare cost of compliance activities for the three regulatory scenarios, the year or years in which all costs are expended are determined and the costs are then calculated as a net present value. For the purposes of this EA, one-time and yearly costs were projected over a 25-year time period to allow comparison with other drinking water regulations using the same analysis period. For this analysis, the net present values of costs in 2007 dollars are calculated using discount rates of three percent and seven percent. These present value costs are then annualized over the 25-year period using the two discount rates.

Exhibit VI-15 summarizes the comparison of total and net change in annualized present value costs of the RTCR and Alternative option relative to the 1989 TCR baseline. A continuation of the 1989 TCR will result in no net change in costs. In calculating the 1989 TCR baseline, not all activities that PWSs and States are performing under the 1989 TCR were quantified (see Exhibit VI-16 of this preamble). Some of these activities are not required under the 1989 TCR but PWSs are performing them nonetheless (e.g., corrective actions); or these activities are required under the 1989 TCR and PWSs and States will continue to perform them under either the RTCR or Alternative option (e.g., revising sample siting plans). Instead of determining the absolute costs of performing these activities, EPA estimated the net increase in costs from these activities as a result of implementing either the RTCR or the Alternative option.

The net change in mean annualized national costs of the RTCR option relative to the 1989 TCR is estimated to be approximately \$14M using either a three percent or seven percent discount rate. The net change in mean annualized national costs for the Alternative option relative to the 1989 TCR are estimated to be approximately \$30M using a three percent discount rate and \$32M using a seven percent discount rate.

Under the RTCR, public water systems are estimated to incur greater than 90 percent of the RTCR’s net annualized costs. States are expected to incur the remaining costs.

Exhibit VI-15 Comparison of Total and Net Change from 1989 TCR in Annualized Costs (\$Millions, 2007\$)

	PWSs	State	Total	PWSs	State	Total
	3% Discount Rate			7% Discount Rate		
	1989 TCR: Baseline ¹	185	0.9	186	178	0.9
RTCR: Baseline + Incremental ²	199	1.1	200	192	1.3	193
RTCR: Net Change	14	0.1	14	14	0.4	14
RTCR: Percent Change	8%	16%	8%	8%	48%	8%
Alternative option: Baseline + Incremental ²	214	1.2	216	209	1.5	210
Alternative option: Net Change	29	0.3	30	31	0.6	32
Alternative option: Percent Change	16%	34%	16%	17%	69%	18%

Note: Detail may not add due to independent rounding.

Source: RTCR EA (USEPA 2012a).

¹ Does not quantify all 1989 TCR components.

² For components not quantified for the 1989 TCR, only the net increase in the costs of these components is considered for the RTCR and Alternative option (e.g., corrective action costs).

Exhibit VI-16 presents the comparison of total and net change in annualized costs for PWSs and States by rule component. The table shows that corrective action costs are the most significant contributors to the net increase in costs for PWSs under the RTCR. For the Alternative option, routine monitoring costs are the most significant contributor to the net increase in costs for PWSs. For States, revision of sample siting plans contributes most to the

cost increase under the RTCR and Alternative option. For both PWSs and States, a net decrease in costs associated with PN requirements helps to offset the total net cost increase.

Exhibit VI-16 Comparison of Total and Net Change in Annualized Costs by Rule Component (\$Millions, 2007\$)

	PWSs	State	Total	PWSs	State	Total
	3% Discount Rate			7% Discount Rate		
Rule Implementation and Annual Administration						
1989 TCR – Total	-	-	-	-	-	-
RTCR – Total	2.77	0.18	2.95	4.00	0.26	4.26
RTCR – Net Change	2.77	0.18	2.95	4.00	0.26	4.26
Alternative Option – Total	2.77	0.18	2.95	4.00	0.26	4.26
Alternative Option – Net Change	2.77	0.18	2.95	4.00	0.26	4.26
Sample Siting Plan Revision						
1989 TCR – Total	-	-	-	-	-	-
RTCR – Total	0.59	0.42	1.01	0.84	0.59	1.42
RTCR – Net Change	0.59	0.42	1.01	0.84	0.59	1.42
Alternative Option – Total	0.59	0.42	1.01	0.84	0.59	1.42
Alternative Option – Net Change	0.59	0.42	1.01	0.84	0.59	1.42
Routine Monitoring						
1989 TCR – Total	170.59	-	170.59	163.94	-	163.94
RTCR – Total	174.71	-	174.71	167.74	-	167.74
RTCR – Net Change	4.12	-	4.12	3.80	-	3.80
Alternative Option – Total	187.50	-	187.50	182.48	-	182.48
Alternative Option – Net Change	16.91	-	16.91	18.54	-	18.54
Additional Routine Monitoring						
1989 TCR – Total	3.87	-	3.87	3.72	-	3.72
RTCR – Total	1.12	-	1.12	1.09	-	1.09
RTCR – Net Change	(2.75)	-	(2.75)	(2.63)	-	(2.63)
Alternative Option – Total	0.78	-	0.78	0.66	-	0.66
Alternative Option – Net Change	(3.10)	-	(3.10)	(3.06)	-	(3.06)
Repeat Monitoring						
1989 TCR – Total	5.11	-	5.11	4.92	-	4.92
RTCR – Total	4.88	-	4.88	4.70	-	4.70
RTCR – Net Change	(0.23)	-	(0.23)	(0.22)	-	(0.22)
Alternative Option – Total	5.66	-	5.66	5.59	-	5.59
Alternative Option – Net Change	0.54	-	0.54	0.67	-	0.67
Annual Site Visits						
1989 TCR – Total	-	-	-	-	-	-
RTCR – Total	-	-	-	-	-	-
RTCR – Net Change	-	-	-	-	-	-
Alternative Option – Total	-	-	-	-	-	-
Alternative Option – Net Change	-	-	-	-	-	-
Level 1 Assessment						
1989 TCR – Total	1.13	0.21	1.34	1.08	0.20	1.29
RTCR – Total	1.63	0.20	1.84	1.57	0.20	1.77
RTCR – Net Change	0.51	(0.01)	0.50	0.49	(0.01)	0.48
Alternative Option – Total	1.76	0.23	1.99	1.72	0.23	1.94
Alternative Option – Net Change	0.63	0.02	0.65	0.63	0.02	0.65
Level 2 Assessment						
1989 TCR – Total	0.70	0.26	0.96	0.68	0.25	0.92

RTCR – Total	0.90	0.19	1.08	0.88	0.18	1.06
RTCR – Net Change	0.20	(0.07)	0.12	0.20	(0.07)	0.13
Alternative Option – Total	1.26	0.29	1.55	1.30	0.31	1.61
Alternative Option – Net Change	0.55	0.03	0.58	0.62	0.06	0.68
Corrective Actions Based on Level 1 Assessments						
1989 TCR – Total	-	-	-	-	-	-
RTCR – Total	9.62	0.01	9.63	8.14	0.01	8.15
RTCR – Net Change	9.62	0.01	9.63	8.14	0.01	8.15
Alternative Option – Total	10.01	0.01	10.02	8.52	0.01	8.53
Alternative Option – Net Change	10.01	0.01	10.02	8.52	0.01	8.53
Corrective Actions Based on Level 2 Assessments						
1989 TCR – Total	-	-	-	-	-	-
RTCR – Total	2.82	0.00	2.82	2.49	0.00	2.49
RTCR – Net Change	2.82	0.00	2.82	2.49	0.00	2.49
Alternative Option – Total	3.78	0.01	3.79	3.57	0.01	3.58
Alternative Option – Net Change	3.78	0.01	3.79	3.57	0.01	3.58
Public Notification						
1989 TCR – Total	3.75	0.44	4.19	3.60	0.42	4.02
RTCR – Total	0.26	0.06	0.32	0.25	0.06	0.31
RTCR – Net Change	(3.49)	(0.38)	(3.86)	(3.35)	(0.36)	(3.71)
Alternative Option – Total	0.35	0.08	0.43	0.35	0.08	0.44
Alternative Option – Net Change	(3.40)	(0.36)	(3.76)	(3.25)	(0.34)	(3.58)

Note: Detail may not add due to independent rounding.

Assumes a certain level of assessment activity already occurs under the 1989 TCR, as discussed in Chapter 7 of the RTCR EA (USEPA 2012a).

Not all 1989 TCR components are quantified. For components not quantified for the 1989 TCR, only the net increase in the costs of these components is considered for the RTCR and Alternative option (e.g., corrective action costs).

Source: RTCR EA (USEPA 2012a)

2. PWS costs

Like the 1989 TCR, the RTCR applies to all PWSs. Exhibit VI-17 presents the total and net change in annualized costs to PWSs by size and type for the three regulatory options. No net change in costs will result from a continuation of the 1989 TCR. Among PWSs serving 4,100 or fewer people, looking at the three percent discount rate, the largest increase in aggregate net costs is incurred by the TNCWSs serving 100 or fewer people under either the RTCR (\$5.3M) or Alternative option (\$14.7M) because of the large number of systems. On a per system basis, this translates to a net annualized present value increase of approximately \$86 per system under the RTCR and \$240 per system under the Alternative option for the TNCWSs serving 100 or fewer people. As described in section VII.C of this preamble, *Regulatory Flexibility Act (RFA)*, none

of the small TNCWSs are estimated to have costs that are greater than or equal to three percent of their revenue and only 61 small systems (0.04%) are estimated to have costs greater than or equal to one percent of their revenue.

The total net change in national annualized present value costs for all PWSs serving greater than 4,100 people (approximately \$5.6M using three percent discount rate) is the same under the RTCR and Alternative option. This is expected because the provisions for PWSs serving greater than 4,100 are the same under the RTCR and the Alternative option. Monitoring requirements for PWSs serving greater than 4,100 people remain essentially unchanged under either the RTCR or Alternative option. The observed overall net increase in costs for PWSs serving greater than 4,100 people is driven primarily by the requirements to conduct assessments and to correct any sanitary defects that are found.

Exhibit VI-17 Total and Net Change in Annualized Costs to PWSs by PWS Size and Type (\$Millions, 2007\$)

PWS Size (Population Served)	3% Discount Rate					7% Discount Rate				
	1989 TCR Total	RTCR Total	RTCR Net	Alternative Option Total	Alternative Option Net	1989 TCR Total	RTCR Total	RTCR Net	Alternative Option Total	Alternative Option Net
	A	B	C=B-A	D	E=D-A	F	G	H=G-F	I	J=I-F
Community Water Systems (CWSs)										
≤100	7.4	7.5	0.1	7.6	0.2	7.1	7.3	0.2	7.5	0.3
101-500	9.0	9.4	0.4	9.5	0.5	8.6	9.1	0.5	9.2	0.6
501-1,000	3.7	3.8	0.0	3.8	0.1	3.6	3.7	0.1	3.7	0.1
1,001-4,100	13.2	13.6	0.4	13.6	0.4	12.7	13.1	0.4	13.1	0.4
4,101-33K	42.4	44.8	2.4	44.8	2.4	40.7	42.8	2.1	42.8	2.1
33,001-96K	34.9	36.4	1.5	36.4	1.5	33.5	34.8	1.3	34.8	1.3
96,001-500K	34.7	36.2	1.5	36.2	1.5	33.4	34.6	1.2	34.6	1.2
500,001-1M	6.5	6.7	0.2	6.7	0.2	6.2	6.4	0.1	6.4	0.1
>1M	5.6	5.6	(0.0)	5.6	(0.0)	5.3	5.3	(0.0)	5.3	(0.0)
Total	157.4	163.9	6.5	164.1	6.7	151.3	157.2	5.9	157.5	6.2
Nontransient Noncommunity Water Systems (NTNCWSs)										
≤100	2.6	2.7	0.1	3.7	1.1	2.5	2.7	0.2	3.8	1.4
101-500	1.9	2.0	0.1	2.8	0.9	1.8	2.0	0.2	2.9	1.1
501-1,000	0.6	0.6	0.1	0.9	0.3	0.6	0.6	0.1	0.9	0.3
1,001-4,100	1.2	1.3	0.1	1.3	0.1	1.1	1.2	0.1	1.2	0.1
4,101-33K	0.4	0.5	0.1	0.5	0.1	0.4	0.5	0.0	0.5	0.0
33,001-96K	0.1	0.1	0.0	0.1	0.0	0.1	0.1	0.0	0.1	0.0
96,001-500K	0.1	0.1	(0.0)	0.1	(0.0)	0.1	0.1	(0.0)	0.1	(0.0)
500,001-1M	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
>1M	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Total	6.9	7.3	0.4	9.3	2.5	6.6	7.2	0.6	9.6	3.0
Transient Noncommunity Water Systems (TNCWSs)										
≤100	13.4	18.7	5.3	28.1	14.7	12.8	18.2	5.3	28.9	16.1
101-500	4.9	6.5	1.6	9.5	4.7	4.7	6.3	1.6	9.8	5.1

501-1,000	0.6	0.8	0.2	1.2	0.5	0.6	0.8	0.2	1.2	0.6
1,001-4,100	0.9	1.0	0.1	1.0	0.1	0.9	1.0	0.1	1.0	0.1
4,101-33K	0.4	0.5	0.1	0.5	0.1	0.4	0.5	0.0	0.5	0.0
33,001-96K	0.1	0.1	(0.0)	0.1	(0.0)	0.1	0.1	(0.0)	0.1	(0.0)
96,001-500K	0.1	0.1	(0.0)	0.1	(0.0)	0.1	0.1	(0.0)	0.1	(0.0)
500,001-1M	0.2	0.2	(0.0)	0.2	(0.0)	0.2	0.2	(0.0)	0.2	(0.0)
>1M	0.3	0.3	0.0	0.3	0.0	0.3	0.3	0.0	0.3	0.0
Total	20.9	28.1	7.3	41.0	20.1	20.1	27.3	7.3	42.0	21.9
Grand Total	185.2	199.3	14.2	214.4	29.3	177.9	191.7	13.8	209.0	31.1

Note: Detail may not add due to independent rounding. Because only the incremental costs of some rule components are considered as part of the cost analysis, references to “total” costs in this exhibit do not refer to complete costs for regulatory implementation but only to specific costs considered to calculate net change in costs. Source: RTCR cost model.

The following subsections discuss the different components of the costs to PWSs: rule implementation and annual administration, sample siting plan revision, monitoring, annual site visits, assessments, corrective actions, and public notification.

a. Rule implementation and annual administration. Under the RTCR and Alternative option, all PWSs subject to the RTCR incur one-time costs that include time for staff to read the RTCR, become familiar with its provisions, and to train employees on rule requirements. No additional implementation burden or costs will be incurred by PWSs if the 1989 TCR option is maintained. Under the RTCR and Alternative option, all PWSs subject to the RTCR perform additional or transitional implementation activities. Based on previous experience with rule implementation, EPA estimated that PWSs require a total of four hours to read and understand the rule, and a total of eight hours to plan and assign appropriate personnel and resources to carry out rule activities. EPA estimated a net increase in national annualized cost estimates incurred by PWSs for rule implementation and annual administration of \$2.77M (three percent discount rate) and \$4.00M (seven percent discount rate) under either the RTCR or the Alternative option. The annualized net present value total and net change cost estimates for PWSs for rule implementation and annual administration under the 1989 TCR, RTCR, and Alternative option are presented in Exhibit VI-16 of this preamble.

b. Sample siting plan revision. Under the RTCR and Alternative option, all PWSs subject to the RTCR incur one-time costs to revise existing sample siting plans to identify sampling locations and collection schedules that are representative of water throughout the distribution system. Under the 1989 TCR, no additional burden or costs are expected to be incurred by PWSs to revise sample siting plans, as these PWSs are already collecting total coliform samples in accordance with a written sample siting plan. Based on previous experience, EPA estimated that PWSs require two to eight hours to revise their sample siting plan, depending on PWS size. EPA estimated a net increase in national annualized cost estimates incurred by PWSs for revising sample siting plans of \$0.59M (three percent discount rate) and \$0.84M (seven percent discount rate) under either the RTCR or the Alternative option. The annualized net present value total and net change cost estimates for PWSs to revise their sample siting plan under the 1989 TCR, RTCR, and Alternative option are presented in Exhibit VI-16 of this preamble.

c. Monitoring. Monitoring costs for PWSs are calculated by multiplying the total numbers of routine, additional routine, and repeat samples required under the 1989 TCR, RTCR, and Alternative options by the monitoring costs per sample. Under the RTCR, the increased stringency to qualify for reduced monitoring results in more routine samples being taken over time (fewer PWSs are on reduced monitoring) compared to the 1989 TCR. For the Alternative option, this effect is combined with the requirement that all PWSs start the implementation period on monthly monitoring. The Alternative option also prohibits annual monitoring, resulting in a greater increase in the number of routine samples compared to the RTCR. Costs for routine monitoring under the RTCR and Alternative option are higher than routine monitoring costs under the 1989 TCR.

The overall reductions in the numbers of additional routine samples required under the RTCR and Alternative option result in lower costs for additional routine monitoring when compared to the 1989 TCR. Under the RTCR and Alternative option, additional routine monitoring is no longer required for systems that monitor at least monthly, and when additional routine monitoring is required, the number of samples required is reduced from five to three. Cost reductions are greater under the Alternative option than under the RTCR because under the Alternative option all PWSs start on monthly monitoring and are not required to take additional routine samples during that period.

Costs for repeat sampling are also lower under the RTCR and Alternative option. Under the 1989 TCR, PWSs serving 1,000 or fewer people take four repeat samples, at and within five service connections upstream and downstream of the initial total coliform positive occurrence location, over the course of 24 hours following the event. Under the RTCR and Alternative option, PWSs serving 1,000 or fewer people will need to take only three repeat samples, and they have greater flexibility about where to take them, consistent with the system sample siting plan that is developed in accordance with RTCR requirements and subject to review and revision by the State. The number of repeat samples required for PWSs serving more than 1,000 people is the same under the 1989 TCR and the RTCR and Alternative option, although these systems also have greater flexibility in sample location.

Exhibit VI-18 summarizes the cumulative number of samples taken by PWS size and category for routine, additional, and repeat monitoring under the 1989 TCR, RTCR, and Alternative option over the entire 25-year period of analysis. Under the 1989 TCR option, approximately 82.1M samples are taken over the 25-year period of analysis compared to approximately 82.2M samples under the RTCR and approximately 87.9M samples under the

Alternative option (less than 10 percent more than 1989 TCR option). Appendix A of the RTCR EA presents additional information on the number of samples taken each year during the analysis period.

Exhibit VI-18 Cumulative Number of Samples over 25-Year Period of Analysis for Baseline (1989 TCR) and Regulatory Alternatives (RTCR and Alternative option)

PWS Size (Population Served)	1989 TCR			RTCR			Alternative		
	Routine Monitoring Samples	Additional Routine Monitoring Samples	Repeat Monitoring Samples	Routine Monitoring Samples	Additional Routine Monitoring Samples	Repeat Monitoring Samples	Routine Monitoring Samples	Additional Routine Monitoring Samples	Repeat Monitoring Samples
	A	B	C	D	E	F	G	H	I
Community Water Systems (CWSs) – Surface Water									
≤100	304,247	23,167	18,698	308,880	-	13,764	308,880	-	13,764
101-500	562,198	27,009	21,684	567,600	-	15,660	567,600	-	15,660
501-1,000	306,605	15,334	12,299	309,672	-	8,708	309,672	-	8,708
1,001-4,100	1,921,237	55,132	33,729	1,951,224	-	33,326	1,951,224	-	33,326
4,101-33K	10,636,296	-	186,729	10,636,296	-	181,661	10,636,296	-	181,661
33,001-96K	11,058,960	-	194,149	11,058,960	-	188,880	11,058,960	-	188,880
96,001-500K	10,190,400	-	178,901	10,190,400	-	174,046	10,190,400	-	174,046
500,001-1M	2,019,600	-	35,456	2,019,600	-	34,493	2,019,600	-	34,493
>1M	1,686,960	-	29,616	1,686,960	-	28,812	1,686,960	-	28,812
Total	38,686,502	120,642	711,259	38,729,592	-	679,350	38,729,592	-	679,350
Community Water Systems (CWSs) – Ground Water									
≤100	2,815,951	286,073	194,462	2,870,075	8,760	156,897	2,908,469	7,545	158,439
101-500	3,344,578	243,895	171,252	3,391,200	6,127	136,906	3,428,876	5,264	137,959
501-1,000	1,072,202	70,803	51,673	1,085,730	1,844	39,659	1,098,488	1,616	39,580
1,001-4,100	3,997,293	160,710	100,618	4,079,328	-	96,939	4,079,328	-	96,939
4,101-33K	9,145,224	-	230,201	9,145,224	-	217,321	9,145,224	-	217,321
33,001-96K	4,884,000	-	122,938	4,884,000	-	116,060	4,884,000	-	116,060
96,001-500K	1,945,680	-	48,976	1,945,680	-	46,236	1,945,680	-	46,236
500,001-1M	253,440	-	6,380	253,440	-	6,023	253,440	-	6,023
>1M	269,280	-	6,778	269,280	-	6,399	269,280	-	6,399
Total	27,727,648	761,481	933,279	27,923,956	16,731	822,439	28,012,784	14,425	824,956
Nontransient Noncommunity Water Systems (NTNCWSs) – Surface Water									
≤100	65,018	4,910	3,991	66,000	-	3,040	66,000	-	3,040
101-500	66,045	3,735	3,011	66,792	-	2,169	66,792	-	2,169
501-1,000	22,976	1,278	1,029	23,232	-	756	23,232	-	756
1,001-4,100	41,759	2,142	1,348	42,768	-	1,228	42,768	-	1,228
4,101-33K	50,424	-	1,628	50,424	-	1,448	50,424	-	1,448
33,001-96K	34,320	-	1,108	34,320	-	985	34,320	-	985
96,001-500K	31,680	-	1,023	31,680	-	910	31,680	-	910
500,001-1M	-	-	-	-	-	-	-	-	-
>1M	-	-	-	-	-	-	-	-	-
Total	312,223	12,065	13,138	315,216	-	10,536	315,216	-	10,536
Nontransient Noncommunity Water Systems (NTNCWSs) – Ground Water									
≤100	971,538	128,775	84,992	932,025	48,142	68,123	1,314,175	36,965	91,416
101-500	725,785	66,525	43,597	678,688	25,630	35,860	976,627	19,382	48,269
501-1,000	190,649	16,037	10,680	180,145	6,166	8,601	249,760	4,802	11,817
1,001-4,100	460,470	28,214	17,790	473,352	-	15,887	473,352	-	15,887
4,101-33K	153,648	-	5,936	153,648	-	5,157	153,648	-	5,157
33,001-96K	23,760	-	918	23,760	-	797	23,760	-	797
96,001-500K	-	-	-	-	-	-	-	-	-

500,001-1M	-	-	-	-	-	-	-	-	-
>1M	-	-	-	-	-	-	-	-	-
Total	2,525,850	239,551	163,913	2,441,617	79,938	134,426	3,191,322	61,149	173,343
Transient Noncommunity Water Systems (TNCWSs) – Surface Water									
≤100	345,401	40,475	33,065	353,496	-	23,122	353,496	-	23,122
101-500	128,156	15,261	12,454	131,208	-	8,192	131,208	-	8,192
501-1,000	22,691	2,704	2,207	23,232	-	1,533	23,232	-	1,533
1,001-4,100	40,151	4,155	2,707	42,240	-	2,312	42,240	-	2,312
4,101-33K	40,656	-	-	40,656	-	2,225	40,656	-	2,225
33,001-96K	-	-	-	-	-	-	-	-	-
96,001-500K	-	-	-	-	-	-	-	-	-
500,001-1M	-	-	-	-	-	-	-	-	-
>1M	102,960	-	-	102,960	-	5,636	102,960	-	5,636
Total	680,015	62,596	50,434	693,792	-	43,020	693,792	-	43,020
Transient Noncommunity Water Systems (TNCWSs) – Ground Water									
≤100	4,493,808	905,554	600,315	6,076,163	446,166	631,105	9,524,123	333,524	912,589
101-500	1,614,924	316,238	210,714	1,940,946	135,822	194,697	3,021,771	104,732	282,740
501-1,000	177,264	32,730	22,064	206,130	14,078	20,078	304,534	10,412	27,932
1,001-4,100	335,283	29,957	19,113	348,480	-	16,027	348,480	-	16,027
4,101-33K	156,288	-	8,909	156,288	-	7,188	156,288	-	7,188
33,001-96K	34,320	-	1,956	34,320	-	1,578	34,320	-	1,578
96,001-500K	26,400	-	1,505	26,400	-	1,214	26,400	-	1,214
500,001-1M	63,360	-	3,612	63,360	-	2,914	63,360	-	2,914
>1M	-	-	-	-	-	-	-	-	-
Total	6,901,647	1,284,478	868,188	8,852,088	596,065	874,801	13,479,275	448,667	1,252,181
Grand Total	76,833,885	2,480,814	2,740,210	78,956,260	692,734	2,564,572	84,421,981	524,241	2,983,387

Note: (B), (E), (H) For modeling purposes, additional routine sample counts include regular routine samples taken in the same month.
Source: Appendix A of the RTCR EA (USEPA 2012a) – Total PWS Counts (A.1z, A.2z, A.3z).

The annualized total and net change cost estimates for PWSs to perform monitoring under the 1989 TCR, RTCR, and Alternative option are presented in Exhibit VI-19. EPA estimated a net increase in national annualized cost estimates incurred by PWSs for monitoring of \$1.14M (three percent discount rate) and \$0.95M (seven percent discount rate) under the RTCR and a net increase of \$14.36M (three percent discount rate) and \$16.15M (seven percent discount rate) under the Alternative option. See also Exhibit VI-16 of this preamble for a breakdown on the costs of monitoring (i.e., routine, additional routine, repeat).

Exhibit VI-19 Annualized National PWS Monitoring Cost Estimates (\$Millions, 2007\$)

	3% discount rate	7% discount rate
1989 TCR - Total	\$ 179.57	\$ 172.57
RTCR – Total	\$ 180.71	\$ 173.52
RTCR - Net Change	\$ 1.14	\$ 0.95
RTCR - Percent Change	0.63%	0.55%
Alternative option – Total	\$ 193.93	\$ 188.72

Alternative option - Net Change	\$ 14.36	\$ 16.15
Alternative option - Percent Change	7.99%	9.36%

Note: Detail may not add due to independent rounding.

Source: RTCR EA (USEPA 2012a)

The overall estimated increase in monitoring costs seen under the RTCR is driven by increases in routine monitoring due to stricter requirements to qualify for reduced monitoring. However, this is mostly offset by reductions in additional routine and repeat monitoring. For the Alternative option, the requirement for all PWSs to sample on a monthly basis at the beginning of rule implementation results in a much larger cost differential that is only partially offset by reduced costs from reductions in additional routine monitoring requirements.

d. Annual site visits. Under the RTCR, any PWS on an annual monitoring schedule is required to also have an annual site visit conducted by the State or State-designated third party. A voluntary Level 2 site assessment can also satisfy the annual site visit requirement. For years in which the State performs a sanitary survey (at least every five years for NCWSs and three years for CWSs), a sanitary survey performed during the same year can also be used to satisfy this requirement. Although similar site visits are not currently required under the 1989 TCR, discussions with States during the TCRDSAC proceedings revealed that some do, in fact, conduct such site visits for PWSs on annual monitoring schedules. Because of the high cost for an annual site visit by a State, for this analysis EPA assumed that no States choose to conduct annual site visits unless they already do so under the 1989 TCR. Therefore, for overall costing purposes, no net change in PWS or State costs are assumed for annual monitoring site visits under the RTCR or Alternative option.

e. Assessments. Annualized cost estimates for Level 1 and Level 2 assessments under the 1989 TCR, RTCR, and Alternative option are calculated in the RTCR EA by multiplying the

number of assessments estimated by the predictive modeling (summarized in Exhibit 7.13 of the EA) by the unit costs (summarized in Exhibits 7-11 and 7-12 of the EA). Appendix A of the RTCR EA provides a detailed breakout of the number of Level 1 and Level 2 assessments estimated by the occurrence model. EPA estimated a net increase in national annualized cost estimates incurred by PWSs for conducting assessment of \$0.70M (three percent discount rate) and \$0.69M (seven percent discount rate) under the RTCR and a net increase of \$1.18M (three percent discount rate) and \$1.25M (seven percent discount rate) under the Alternative option. Annualized cost estimates are presented in Exhibit VI-16 of this preamble.

Under the RTCR, all PWSs are required to conduct assessments of their systems when they exceed Level 1 or Level 2 treatment technique triggers. While PWSs are not required to conduct assessments under the 1989 TCR, some PWSs do currently engage in assessment activity (which may or may not meet the RTCR criteria) following non-acute and acute MCL violations. EPA estimates both the costs to PWSs to conduct assessments under the RTCR as well as the level of effort that PWSs already put toward assessment activities under the 1989 TCR. These estimates are based on the work of the stakeholders in the Technical Work Group (TWG) during the proceedings of the TCRDSAC. These estimates allowed EPA to determine the average net costs to conduct assessments under the RTCR. EPA assumes that the numbers of non-acute and acute MCL violations would remain steady under a continuation of the 1989 TCR based on the review of SDWIS/FED violation data. Under the RTCR, EPA assumes that the numbers of assessment triggers decrease over time from the steady state level estimate based on the 1989 TCR to a new steady state level, as a result of reduced fecal indicator occurrence associated with the beneficial effects of requiring assessments and corrective action.

The overall number of assessments is larger under the Alternative option compared to the RTCR option. This is a result of the initial monthly monitoring requirements for all PWSs under the Alternative option. The modeling results indicate that a greater number of samples early in the implementation period results in more positive samples and associated assessments despite the predicted long term reductions in occurrence as informed by the assumptions. This increase in total assessments performed, combined with the higher unit cost of performing assessments compared to existing practices under the 1989 TCR, results in a higher net cost increase for the Alternative option than under the RTCR. The total net increase in cost for the Alternative option is estimated to be nearly twice that of the RTCR option. See Exhibit 7.15 of the RTCR EA.

f. Corrective actions. Under the RTCR and Alternative option, all PWSs are required to correct sanitary defects found through the performance of Level 1 or Level 2 assessments. For modeling purposes, EPA estimated the net change in the number of corrective actions performed under the RTCR and Alternative option. For ground water systems, EPA assumed that any corrective actions based on a positive source water sample are accounted for under the GWR and not under the RTCR. Based on discussions with State representatives, EPA assumed that an additional 10 percent of corrective actions will be performed as a result of the assessment and corrective action requirements of the RTCR, representing the net increase of the RTCR over the 1989 TCR.

To estimate the costs incurred for the correction of sanitary defects, EPA assumed the percent distribution of PWSs that perform different types of corrective actions as presented in the compliance forecast shown in Exhibit VI-20 (i.e., distribution of the additional 10 percent of corrective actions) based on best professional judgment and stakeholder input. The compliance forecast presented in this section was informed by discussions of the TCRDSAC Technical Work

Group and focuses on broad categories of types of corrective actions anticipated. EPA used best professional judgment and stakeholder input to make simplifying assumptions on the distribution of these categories that are implemented by different systems based on size and type of system. For each of the categories listed, a PWS is assumed to take a specific action that falls under that general category. Detailed compliance forecasts showing the specific corrective actions used in the cost analysis are provided in Appendix D of the RTCR EA, along with summary tables of the unit costs used in the analysis. Each corrective action in the detailed compliance forecast is also assigned a representative unit cost. Detailed descriptions of the derivation of unit costs are provided in Exhibits 5-1 through 5-47 of the *Technology and Cost Document for the Revised Total Coliform Rule* (USEPA 2012b).

Exhibit VI-20 Compliance Forecast for Corrective Actions based on Level 1 and Level 2 Assessments

PWS Size (Population Served)	PWS Flushing	Sampler Training	Replace/Repair of Distribution System Components	Maintenance of Adequate Pressure	Maintenance of Appropriate Hydraulic Residence Time	Storage Facility Maintenance	Booster Disinfection	Cross-connection Control and Backflow Prevention	Addition or Upgrade of Online Monitoring and Control	Addition of Security Measures	Development and Implementation of an Operations Plan
	A	B	C	D	E	F	G	H	I	J	K
Level 1 Compliance Forecast											
≤100	39%	15%	12%	9%	8%	6%	4%	1%	3%	1%	2%
101-500	39%	15%	12%	9%	8%	6%	4%	1%	3%	1%	2%
501-1,000	39%	15%	12%	9%	8%	6%	4%	1%	3%	1%	2%
1,001-4,100	39%	15%	12%	9%	8%	6%	4%	1%	3%	1%	2%
4,101-33K	39%	15%	12%	9%	8%	6%	4%	1%	3%	1%	2%
33,001-96K	39%	15%	12%	9%	8%	6%	4%	1%	3%	1%	2%
96,001-500K	39%	15%	12%	9%	8%	6%	4%	1%	3%	1%	2%
500,001-1M	39%	15%	12%	9%	8%	6%	4%	1%	3%	1%	2%
>1M	39%	15%	12%	9%	8%	6%	4%	1%	3%	1%	2%
Level 2 Compliance Forecast											
≤100	15%	4%	18%	15%	15%	11%	8%	2%	6%	2%	4%
101-500	15%	4%	18%	15%	15%	11%	8%	2%	6%	2%	4%
501-1,000	15%	4%	18%	15%	15%	11%	8%	2%	6%	2%	4%
1,001-4,100	15%	4%	18%	15%	15%	11%	8%	2%	6%	2%	4%
4,101-33K	15%	4%	18%	15%	15%	11%	8%	2%	6%	2%	4%
33,001-96K	15%	4%	18%	15%	15%	11%	8%	2%	6%	2%	4%
96,001-500K	15%	4%	18%	15%	15%	11%	8%	2%	6%	2%	4%
500,001-1M	15%	4%	18%	15%	15%	11%	8%	2%	6%	2%	4%
>1M	15%	4%	18%	15%	15%	11%	8%	2%	6%	2%	4%

Source: (A) – (K) Percent of PWSs performing corrective actions based on Level 1 and Level 2 assessments reflect EPA estimates.

Level 1 assessments generally are less involved than Level 2 assessments and may result in finding less complex problems. As shown in the compliance forecast in Exhibit VI-20, EPA estimated that corrective actions found through Level 1 assessments result in corrective actions

that focus more on transient solutions or training (columns A and B) than on permanent fixes to the PWS. However, in the case of flushing, EPA assumed that in a majority of instances, PWSs implement a regular flushing program as opposed to a single flushing, based on EPA and stakeholder best professional judgment.

Corrective actions taken as a result of Level 2 assessments are expected to find a higher proportion of structural/technical issues (columns C-K) resulting in material fixes to the PWSs and distribution system. Consistent with the discussions of the TCRDSAC regarding major structural fixes or replacements, EPA did not include these major costs in the analysis. Distribution system appurtenances such as storage tanks and water mains generally have a useful life that is accounted for in water system capital planning. The assessments conducted in response to RTCR triggers could identify when that useful life has ended but are not solely responsible for the need to correct the defect. In addition, EPA ran two sensitivity analyses to assess the potential impacts of different distributions within the compliance forecast. Results of the sensitivity analyses are presented in Exhibit VI-21, which indicates that the low bound estimates of annualized net change in costs at three percent discount rate are approximately \$3M for the RTCR and \$17M for the Alternative option, and the high bound estimates are approximately \$25M for the RTCR and \$43M for the Alternative option. Varying the assumptions about the percentage of corrective actions identified and the effectiveness of those actions had less than a linear effect on outcomes, and the RTCR continues to be less costly than the Alternative option under all scenarios modeled.

Exhibit VI-21 Sensitivity Analysis – Annualized Net Change in Costs Based on Changes in Compliance Forecast (\$Millions, 2007\$)

	PWSs	State	Total	PWSs	State	Total
	3% Discount Rate			7% Discount Rate		
RTCR Net Change	14.15	0.15	14.30	13.75	0.42	14.17
RTCR Low Bound Net Change	2.61	0.15	2.75	3.91	0.42	4.33

RTCR High Bound Net Change	25.10	0.15	25.25	23.63	0.42	24.05
Alternative Option Net Change	29.29	0.31	29.60	31.09	0.61	31.69
Alternative Option Low Bound Net Change	16.54	0.31	16.84	19.93	0.61	20.54
Alternative Option High Bound Net Change	42.68	0.31	42.99	43.63	0.61	44.24

Note: Detail may not add due to independent rounding.

Source: RTCR cost model, described in chapter 7 of the RTCR EA (USEPA 2012a).

As indicated in the more detailed analysis presented in chapter 7 of the RTCR EA, PWSs also incur reporting and recordkeeping burden to notify the State upon completion of each corrective action. PWSs may also consult with the State or with outside parties to determine the appropriate corrective action to be implemented.

Annualized cost estimates for PWSs to perform corrective actions are estimated by multiplying the number of Level 1 and Level 2 corrective actions estimated by the predictive model, (i.e., 10 percent of Level 1 and Level 2 assessments) by the percentages in the compliance forecast and unit costs of corrective actions and associated reporting and recordkeeping. Exhibit 7.13 of the RTCR EA presents the estimated totals of non-acute and acute MCL violations (1989 TCR) and Level 1 and Level 2 assessments (RTCR and Alternative option). The model predicts a total of approximately 109,000 single non-acute MCL violations, 58,000 cases of a second non-acute MCL violation, and 16,000 acute MCL violations for the 1989 TCR, under which some PWSs currently engage in assessment activity which may or may not meet the RTCR criteria (see section 7.4.5 of the RTCR EA for details). For the RTCR, the model predicts approximately 104,000 Level 1 assessments and 52,000 Level 2 assessments. For the Alternative option, the model predicts approximately 120,000 Level 1 assessments and 81,000 Level 2 assessments. EPA estimated a net increase in national annualized cost estimates incurred by PWSs for conducting corrective actions of \$12.44M (three percent discount rate) and \$10.63M (seven percent discount rate) under the RTCR and a net increase of \$13.79M (three percent discount rate) and \$12.09M (seven percent discount rate) under the Alternative option.

The annualized net present value total and net change cost estimates for PWSs to perform corrective actions under the 1989 TCR, RTCR, and Alternative option are presented in Exhibit VI-16 of this preamble.

The differences in the net change in corrective action costs between the RTCR and Alternative option are a function of the different number of assessments estimated to be performed in the predictive model.

g. Public notification. Estimates of PWS unit costs for PN are derived by multiplying PWS labor rates from section 7.2.1 of the RTCR EA and burden hour estimates derived from the *Draft Information Collection Request for the Public Water System Supervision Program* (USEPA 2008b). PWS PN unit cost estimates are presented in Exhibit 7.19 of the RTCR EA.

Total and net change in annualized costs for PN under the RTCR and Alternative option are estimated by multiplying the model estimates of PWSs with acute (Tier 1 public notification) and non-acute (Tier 2 public notification) violations by the PWS unit costs for performing PN activities. The RTCR cost model assumed that all violations are addressed following initial PN, and no burden is incurred by PWSs for repeat notification. EPA estimated a net decrease in national annualized cost estimates incurred by PWSs for public notification of \$3.49M (three percent discount rate) and \$3.35M (seven percent discount rate) under the RTCR and a net decrease of \$3.40M (three percent discount rate) and \$3.25M (seven percent discount rate) under the Alternative option. The annualized total and net cost estimates for PWSs to perform public notification under the 1989 TCR, RTCR, and Alternative option are presented in Exhibit VI-16 of this preamble.

A significant reduction in costs is estimated due to the elimination of Tier 2 public notification for non-acute/monthly MCL violations under both the RTCR and Alternative option.

3. State costs

EPA estimated that States as a group incur a net increase in national annualized present value costs under the RTCR of \$0.2M (at three percent discount rate) and \$0.4M (at seven percent discount rate) and under the Alternative option of \$0.3M (at three percent discount rate) and \$0.6M (at seven percent discount rate). State costs include implementing and administering the rule, revising sample siting plans, reviewing sampling results, conducting annual site visits, reviewing completed assessment forms, tracking corrective actions, and tracking public notifications. The costs presented in the RTCR EA are summary costs; costs to individual states vary based on state programs and the number and types of systems in the state. The following sections summarize the key assumptions that EPA made to estimate the costs of the RTCR and Alternative option to States. Chapter 7 of the RTCR EA provides a description of the analysis.

a. Rule implementation and annual administration. States incur administrative costs to implement the RTCR. These implementation costs are not directly required by specific provisions of the RTCR alternatives, but are necessary for States to ensure the provisions of the RTCR are properly carried out. States need to allocate time for their staff to establish and maintain the programs necessary to comply with the RTCR, including developing and adopting State regulations and modifying data management systems to track new required PWS reports to the States. Time requirements for a variety of State agency activities and responses are estimated in this EA. Exhibit 7.4 of the RTCR EA lists the activities required to revise the program following promulgation of the RTCR along with their respective costs and burden including, for example, the net change in State burden associated with tracking the monitoring frequencies of PWSs (captured under “modify data management systems”). EPA estimated a net increase in national annualized cost estimates incurred by States for rule implementation of \$0.18M (three

percent discount rate) and \$0.26M (seven percent discount rate) under either the RTCR or the Alternative option. Because time requirements for implementation and annual administration activities vary among State agencies, EPA recognizes that the unit costs used to develop national estimates may be an over- or under-estimate for some States. The annualized total and net change cost estimates for States to implement and administer the rule under the 1989 TCR, RTCR, and Alternative options are presented in Exhibit VI-16 of this preamble.

b. Sample siting plan revision. Under the RTCR and Alternative option, States are expected to incur one-time costs to review sample siting plans and recommend any revisions to PWSs. Under the 1989 TCR option, no additional burden or costs are incurred by States to review sample siting plans, as these PWSs' sample siting plans have already been reviewed and approved. State costs are based on the number of PWSs developing revised sample siting plans each year. Based on previous experience, EPA estimated that States require one to four hours to review revised sample siting plans and provide any necessary revisions to PWSs, depending on PWS size. EPA estimated a net increase in national annualized cost estimates incurred by States for reviewing sample siting plans of \$0.42M (three percent discount rate) and \$0.59M (seven percent discount rate) under either the RTCR or the Alternative option. The annualized net present value total and net change cost estimates for States to review and revise sample siting plan under the 1989 TCR, RTCR, and Alternative option are presented in Exhibit VI-16 of this preamble.

c. Monitoring. EPA assumed that States incur a monthly 15-minute burden to review each PWS's sample results under the 1989 TCR. This estimate reflects the method used to calculate reporting and recordkeeping burden under the 1989 TCR in the *Draft Information Collection Request for the Microbial Rules* (USEPA 2008a). Because the existing method calculates cost

on a per PWS basis and the total number of PWSs is the same for cost modeling under the 1989 TCR and the RTCR and Alternative option, the net change in costs for reviewing monitoring results is assumed to be zero for the RTCR and Alternative option (as shown in Exhibit VI-16 of this preamble). Specific actions by States related to positive samples are accounted for under the actions required in response to those samples.

d. Annual site visits. Under the RTCR, any PWS on an annual monitoring schedule is required to also have an annual site visit conducted by the State or State-designated third party. A voluntary Level 2 site assessment can also satisfy the annual site visit requirement. In many cases a sanitary survey performed during the same year can also be used to satisfy this requirement. Although similar site visits are not currently required under the 1989 TCR, discussions with States during the TCRDSAC proceedings revealed that some do, in fact, conduct such site visits for PWSs on annual monitoring schedules. Because of the high cost for an annual site visit by a State, for this analysis EPA assumed that no States choose to conduct annual site visits unless they already do so under the 1989 TCR. Therefore, for overall costing purposes, no net change in State or PWS costs are assumed for annual monitoring site visits under the RTCR or Alternative option (as shown in Exhibit VI-16 of this preamble).

e. Assessments. States incur burden to review completed Level 1 and Level 2 assessment forms required to be filed by PWSs under the RTCR and Alternative option. Although specific forms are not required under the 1989 TCR, EPA assumes that PWSs engage in some form of consultation with the State when they have positive sample results and MCL violations. For costing purposes, EPA assumes that the level of effort required for such consultations under the 1989 TCR is the same as that which would be required for consultations that occur when an assessment is conducted under the RTCR and Alternative option. State costs for the RTCR and

Alternative options are based on the number of PWSs submitting assessment reports. EPA estimated that State burden to review PWS assessment forms ranges from one to eight hours depending on PWS size and type and the level of the assessment. This burden includes any time required to consult with the PWS about the assessment report.

Although some States may choose to conduct assessments for their PWSs, EPA does not quantify these costs. The costs are attributed to PWSs that are responsible for ensuring that assessments are done.

As explained in chapter 7 of the RTCR EA, EPA assumes a certain level of assessment activity already occurs under the 1989 TCR based on discussions with the technical workgroup supporting the advisory committee. Under the RTCR, the overall number of Level 1 and Level 2 assessment triggers decreases compared to the 1989 TCR as a function of reduced occurrence over time. This reduction in assessments under the RTCR is estimated to translate directly to a small national cost savings (\$0.08M at either three or seven percent discount rate) for States. The overall number of Level 1 and Level 2 assessments is higher under the Alternative option as a result of the initial monthly monitoring requirements for all PWSs. The increase in the number of assessments under the Alternative option is estimated to translate directly to a national cost increase (\$0.05M at three percent discount rate and \$0.08M at seven percent discount rate) for States. The annualized net present value total and net change cost estimates for States to review completed Level 1 and Level 2 assessment forms under the 1989 TCR, RTCR, and Alternative option are presented in Exhibit VI-16 of this preamble.

f. Corrective actions. For each corrective action performed under the RTCR and Alternative option, States incur recordkeeping and reporting burden to review assessment forms and coordinate with PWSs. This includes burden incurred from any optional consultations States

may conduct with PWSs or outside parties to determine the appropriate corrective action to be implemented. There are no State costs for corrective action under the 1989 TCR because corrective action is not required under the 1989 TCR. The number of corrective actions under the RTCR is estimated to translate to a national net annualized cost increase to States of \$0.01M at either three or seven percent discount rate. The number of corrective actions under the Alternative option is estimated to translate to a national net annualized cost increase to States of \$0.02M at either three or seven percent discount rate. See Exhibit VI-16 of this preamble.

g. Public notification. Under the 1989 TCR, RTCR, and Alternative option, States incur recordkeeping and reporting burden to provide consultation, review the public notification certification, and file the report of the violation. A significant reduction in costs is estimated due to the elimination of Tier 2 public notification for non-acute MCL violations under the RTCR and Alternative option. Because State costs are calculated on a per-violation basis, State costs decline. Under the Alternative option, some of the decrease in cost is offset by additional Tier 1 public notification from the increase in the number of *E. coli* MCL violations detected. Burden hour estimate for State unit PN costs are derived from the *Draft Information Collection Request for the Public Water System Supervision Program* (USEPA 2008b). EPA estimated a net decrease in national annualized cost estimates incurred by States for public notification of \$0.38M (three percent discount rate) and \$0.36M (seven percent discount rate) under the RTCR and a net decrease of \$0.36M (three percent discount rate) and \$0.34M (seven percent discount rate) under the Alternative option. The annualized net present value total and net change cost estimates for States to track public notifications under the 1989 TCR, RTCR, and Alternative option are presented in Exhibit VI-16 of this preamble.

4. Nonquantifiable costs

EPA believes that all of the rule elements that are the major drivers of the net change in costs from the 1989 TCR have been quantified to the greatest degree possible. However, cost reductions related to fewer monitoring and reporting violations are not specifically accounted for in the cost analysis, and their exclusion from consideration may result in an overestimate of the net increase in cost between the 1989 TCR option and the RTCR or Alternative option.

Furthermore, under the 1989 TCR, RTCR, and Alternative option, Tier 3 public notification for monitoring and reporting violations are assumed to be reported once per year as part of the Consumer Confidence Reports (CCRs). Because of the use of the CCR to communicate Tier 3 public notification on a yearly basis, no cost differential between the current 1989 TCR and the RTCR and Alternative option is estimated in the cost model. However, the advisory committee concluded that significant reductions in monitoring and reporting violations may be realized through the revised regulatory framework of the RTCR, which includes new consequences for failing to comply with monitoring provisions such as the requirement to conduct an assessment or ineligibility for reduced monitoring. These possible reductions have not been quantified. System resources used to process monitoring violation notices for the CCR and respond to customer inquiries about the notices, as well as State resources to remind systems to take samples, may be reduced if significant reductions in monitoring and reporting violations are realized. Exclusion of this potential cost savings may lead to an underestimate of the PN cost savings under both the RTCR and Alternative option.

Additionally, as an underlying assumption to the costing methodology, EPA assumed that all PWSs subject to the RTCR requirements are already complying with the 1989 TCR. There may be some PWSs that are not in full compliance with the 1989 TCR, and if so, additional costs and

benefits may be incurred. EPA does not anticipate non-compliance when performing economic analyses for NPDWRs, therefore those costs and benefits are not captured in this analysis.

G. Potential Impact of the RTCR on Households

The household cost analysis considers the potential increase in a household's annual water bill if a CWS passed the entire cost increase resulting from the rule on to their customers. This analysis is a tool to gauge potential impacts and should not be construed as a precise estimate of potential changes to household water bills. State costs and costs to TNCWSs and NTNCWSs are not included in this analysis since their costs are not typically passed through directly to households. Exhibit VI-22 presents the mean expected increases in annual household costs for all CWSs, including those systems that do not have to take corrective action. Exhibit VI-22 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.

Exhibit VI-22 presents net costs per household under the RTCR and Alternative option for all rule components spread across all CWSs. Comparison to the 1989 TCR shows a cost savings for some households. The average annual water bill is expected to increase by six cents or less on average per year.

While the average increase in annual household water bills to implement the RTCR is well less than a dollar, customers served by a small CWS that have to take corrective actions as a result of the rule incur slightly larger increases in their water bills. The subsequent categories of the exhibit present net costs per household for three different subsets of CWSs: (1) CWSs that perform assessments but no corrective actions, (2) CWSs that perform corrective actions, and (3) CWSs that do not perform assessments or corrective actions. Approximately 67 percent of

households are served by CWSs that perform assessments but do not perform corrective actions over the 25-year period of analysis (because no sanitary defects are found). These households experience a slight cost savings on an annual basis, due to a slight reduction in monitoring and public notification costs. The nine percent of households belonging to CWSs that perform corrective actions over the 25-year period of analysis experience an increase in annual net household costs of less than \$0.70 on average for CWSs serving greater than 4,100 people to approximately \$4.50 on average for CWSs serving 4,100 or fewer people on an annual basis. EPA estimated that 24 percent of households are served by CWSs that do not perform assessments or corrective actions over the 25-year period of analysis because they never exceed an assessment trigger. This group of households served by small systems (4,100 or fewer people) experiences a slight cost change on an annual basis, comparable to those performing assessments but no corrective actions. Overall, the main driver of additional household costs under the RTCR is corrective actions.

Exhibit VI-22 Summary of Net Annual Per-Household Costs for the RTCR (2007\$)

Population Served by PWS	3% Discount Rate		7% Discount Rate	
	RTC Net Cost per Household	Alternative Option Net Cost per Household	RTC Net Cost per Household	Alternative Option Net Cost per Household
All Community Water Systems (CWSs)				
≤4,100	0.08	0.10	0.11	0.13
>4,100	0.05	0.05	0.05	0.05
Total	0.06	0.06	0.05	0.05
Community Water Systems (CWSs) performing Level 1/Level 2 Assessments (and no Corrective Actions)				
≤4,100	(0.22)	(0.19)	(0.16)	(0.13)
>4,100	(0.01)	(0.01)	(0.01)	(0.01)
Total	(0.02)	(0.02)	(0.01)	(0.01)
Community Water Systems (CWSs) performing Corrective Actions				
≤4,100	4.47	4.51	3.93	3.98
>4,100	0.66	0.66	0.55	0.55
Total	0.80	0.80	0.68	0.68
Community Water Systems (CWSs) not performing Level 1/Level 2 Assessments, or Corrective Actions				
≤4,100	(0.00)	0.02	0.04	0.06
>4,100	-	-	-	-
Total	(0.00)	0.00	0.01	0.02

Source: RTCR EA (USEPA 2012a)

H. Incremental Costs and Benefits

The RTCR regulatory options achieve increasing levels of benefits at increasing levels of costs. The regulatory options for this rule, in order of increasing costs and benefits (Option 1 lowest and Option 3 highest) are as follows:

- Option 1: 1989 TCR option
- Option 2: RTCR
- Option 3: Alternative option

Incremental costs and benefits are those that are incurred or realized to reduce potential illnesses and deaths from one alternative to the next more stringent alternative. Estimates of incremental costs and benefits are useful when considering the economic efficiency of different regulatory alternatives considered by EPA. One goal of an incremental analysis is to identify the regulatory alternatives where net social benefits are maximized. However, incremental net benefits analysis is not possible when benefits are discussed qualitatively and are not monetized, as is the case with the RTCR.

However, incremental analysis can still provide information on relative cost-effectiveness of different regulatory options. For the RTCR, only costs were monetized. While benefits were not quantified, an indirect proxy for benefits was quantified. To compare the additional net cost increases and associated incremental benefits of the RTCR and the Alternative option, benefits are presented in terms of corrective actions performed since performance of corrective actions is expected to have the impact that is most directly translatable into potential health benefits.

Exhibit VI-23 shows the incremental cost of the RTCR over the 1989 TCR and the Alternative option over the RTCR for costs annualized using three percent and seven percent discount rates. The non-monetized corrective action endpoints are discounted in order to make

them comparable to monetized endpoints. The relationship between the incremental costs and benefits is examined further with respect to cost effectiveness in section VI.M of this preamble, *Benefit Cost Determination for the RTCR*.

Exhibit VI-23 Incremental Net Change in Annualized Costs (\$Millions, 2007\$) and Benefits (Number of Corrective Actions)

Regulatory Option	Costs (\$Millions)		Benefits (L2 Corrective Actions)	
	3%	7%	3%	7%
1989 TCR	186.1	178.8	No change ³	No change ³
RTCR	200.4	193.0	208	202
Incremental RTCR¹	14.3	14.2	208	202
Alternative Option	215.7	210.5	336	355
Incremental Alternative Option²	15.3	17.5	128	153

¹ Represents the incremental net change of the RTCR over the 1989 TCR option.

² Represents the incremental net change of the Alternative option over the RTCR. Add incremental net change for Alternative option to incremental net change for RTCR to calculate the total net change of the Alternative option over the 1989 TCR option.

Note: The RTCR occurrence model yields the number of corrective actions that are expected to be implemented in addition to (net of) those already implemented under the 1989 TCR. The model does not incorporate an estimate of the number of corrective actions implemented per year under the 1989 TCR and does not yield a total for the RTCR and Alternative option that includes the 1989 TCR corrective actions. Benefits shown include corrective actions based on L2 assessments. Detailed benefits and cost information is provided in Appendices A and C, respectively, of the RTCR EA (USEPA 2012a).

³ As explained in section VI.F.2.f of this preamble, *Corrective actions*, for modeling purposes, EPA estimates the net change only in the number of corrective actions performed under the RTCR and Alternative option compared to the 1989 TCR and thus did not quantify the (non-zero) baseline number of corrective actions performed under the 1989 TCR.

I. Benefits from Simultaneous Reduction of Co-occurring Contaminants

As discussed in section VI.E of this preamble, *Anticipated Benefits of the RTCR*, the potential benefits from the RTCR include avoidance of a full range of health effects from the consumption of fecally contaminated drinking water, including the following: acute and chronic illness, endemic and epidemic disease, waterborne disease outbreaks, and death.

Systems may choose corrective actions that also reduce other drinking water contaminants as a result of the fact that the corrective action eliminates a pathway of potential contamination into the distribution system. For example, eliminating a cross connection reduces the potential for

chemical contamination as well as microbial. Due to a lack of contamination co-occurrence data that could relate to the effect that treatment corrective action may have on contamination entering through distribution system pathways, EPA has not quantified such potential benefits.

J. Change in Risk from Other Contaminants

All surface water systems are already required to disinfect under the SWTR (USEPA 1989b, 54 FR 27486, June 29, 1989) but the RTCR could impact currently undisinfected ground water systems. If a previously undisinfected ground water system chooses disinfection as a corrective action, the disinfectant can react with pipe scale causing increased risk from some contaminants that may be entrained in the pipe scales and other water quality problems. Examples of contaminants that could be released include lead, copper, and arsenic. Disinfection 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 an effective corrosion control program.

Introducing a 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 1998a) and additional consideration of DBP risk has been addressed in the final Stage 2 DBPR (USEPA 2006e). In general, ground water systems are less likely to experience high levels of DBPs than surface water systems because they have lower levels of naturally occurring organic materials that contribute to DBP formation.

EPA does not expect many previously undisinfected systems to add disinfection as a result of either the RTCR or Alternative rule options. Ground water systems that are not currently disinfecting may eventually install disinfection if RTCR distribution system monitoring and

assessments, and/or subsequent source water monitoring required under the GWR, result in the determination that source water treatment is required.

K. Effects of Fecal Contamination and/or Waterborne Pathogens on the General Population and Sensitive Subpopulations

It is anticipated that the requirements of the RTCR will help reduce pathways of entry for fecal contamination and/or waterborne pathogens into the distribution system, thereby reducing risk to both the general population as well as to sensitive subpopulations.

As discussed previously in this preamble, fecal contamination may contain waterborne pathogens including bacteria, viruses, and parasitic protozoa. Waterborne pathogens can cause a variety of illnesses, including acute gastrointestinal illness (AGI) with diarrhea, abdominal discomfort, nausea, vomiting, and other symptoms. Most AGI cases are of short duration and result in mild illness. Other more severe illnesses caused by waterborne pathogens include hemolytic uremic syndrome (HUS) (kidney failure), hepatitis, and bloody diarrhea (WHO 2004). Chronic disease such as irritable bowel syndrome, reduced kidney function, hypertension and reactive arthritis can result from infection by a waterborne agent (Clark *et al.* 2008).

Waterborne pathogens may subsequently infect other people through a variety of other routes (WHO 2004). When humans are exposed to and infected by an enteric pathogen, the pathogen becomes capable of reproducing in the gastrointestinal tract. As a result, healthy humans shed pathogens in their feces for a period ranging from days to weeks. This shedding of pathogens often occurs in the absence of any signs of clinical illness. Regardless of whether a pathogen causes clinical illness in the person who sheds it in his or her feces, the pathogen being shed may infect other people directly by person-to-person spread, contact with contaminated surfaces, and other means, which are collectively referred to as secondary spread.

When sensitive subpopulations are exposed to fecal contamination and/or waterborne pathogens, more severe illness (and sometimes death) can occur. Examples of sensitive subpopulations are provided in chapter 2 of the RTCR EA. The potential health effects associated with sensitive population groups – children, pregnant women, the elderly, and the immunocompromised – are described in the following paragraphs.

1. Risk to children, pregnant women, and the elderly

Children and the elderly are particularly vulnerable to kidney failure (hemolytic uremic syndrome) caused by the pathogenic bacterium *E. coli* O157:H7. Kidney failure in children and the elderly have resulted from waterborne outbreaks due to exposure to *E. coli* O157:H7 from consuming ground water in Cabool, Missouri (Swerdlow *et al.* 1992); Alpine, Wyoming (Olsen *et al.* 2002); Washington County, New York (NY State DOH 2000); and Walkerton, Ontario, Canada (Health Canada 2000).

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

Other waterborne viruses can also be particularly harmful to children. Rotavirus disproportionately affects children less than five years of age (Parashar *et al.* 1998). However, the pentavalent rotavirus vaccine licensed for use in the United States has been shown to be 74 percent effective against rotavirus gastroenteritis of any severity (Dennehy 2008). For echovirus, children are disproportionately at risk of becoming ill once infected (Modlin 1986). According to CDC, echovirus is not a vaccine-preventable disease (CDC 2007).

The elderly are particularly at risk from diarrheal diseases (Glass *et al.* 2000) such as those associated with waterborne pathogens. In the US, approximately 53 percent of diarrheal deaths occur among those older than 74 years of age, and 77 percent of diarrheal deaths occur among those older than 64 years of age. In Cabool, Missouri (Swerdlow *et al.* 1992), a waterborne *E. coli* O157:H7 outbreak in a ground water system resulted in four deaths, all among the elderly. One death occurred from HUS (kidney failure), the others from gastrointestinal illness. Furthermore, hospitalizations due to diarrheal disease are higher in the elderly than younger adults (Glass *et al.* 2000). Average hospital stays for individuals older than 74 years of age due to diarrheal illness are 7.4 days compared to 4.1 days for individuals aged 20 to 49 (Glass *et al.* 2000).

It is anticipated that the requirements of the RTCR will help reduce pathways of entry for fecal contamination and/or waterborne pathogens into the distribution system, thereby reducing risk to both the general population as well as to sensitive subpopulations such as children, pregnant women, and the elderly.

2. Risk to immunocompromised persons

AGI symptoms may be more severe in immunocompromised persons (Frisby *et al.* 1997; Carey *et al.* 2004). Such persons include those with acquired immune deficiency syndrome

(AIDS), cancer patients undergoing chemotherapy, organ transplant recipients treated with drugs that suppress the immune system, and patients with autoimmune disorders such as lupus. In AIDS patients, *Cryptosporidium*, a waterborne protozoa, has been found in the lungs, ear, stomach, bile duct, and pancreas in addition to the small intestine (Farthing 2000). Immunocompromised patients with severe persistent cryptosporidiosis may die (Carey *et al.* 2004).

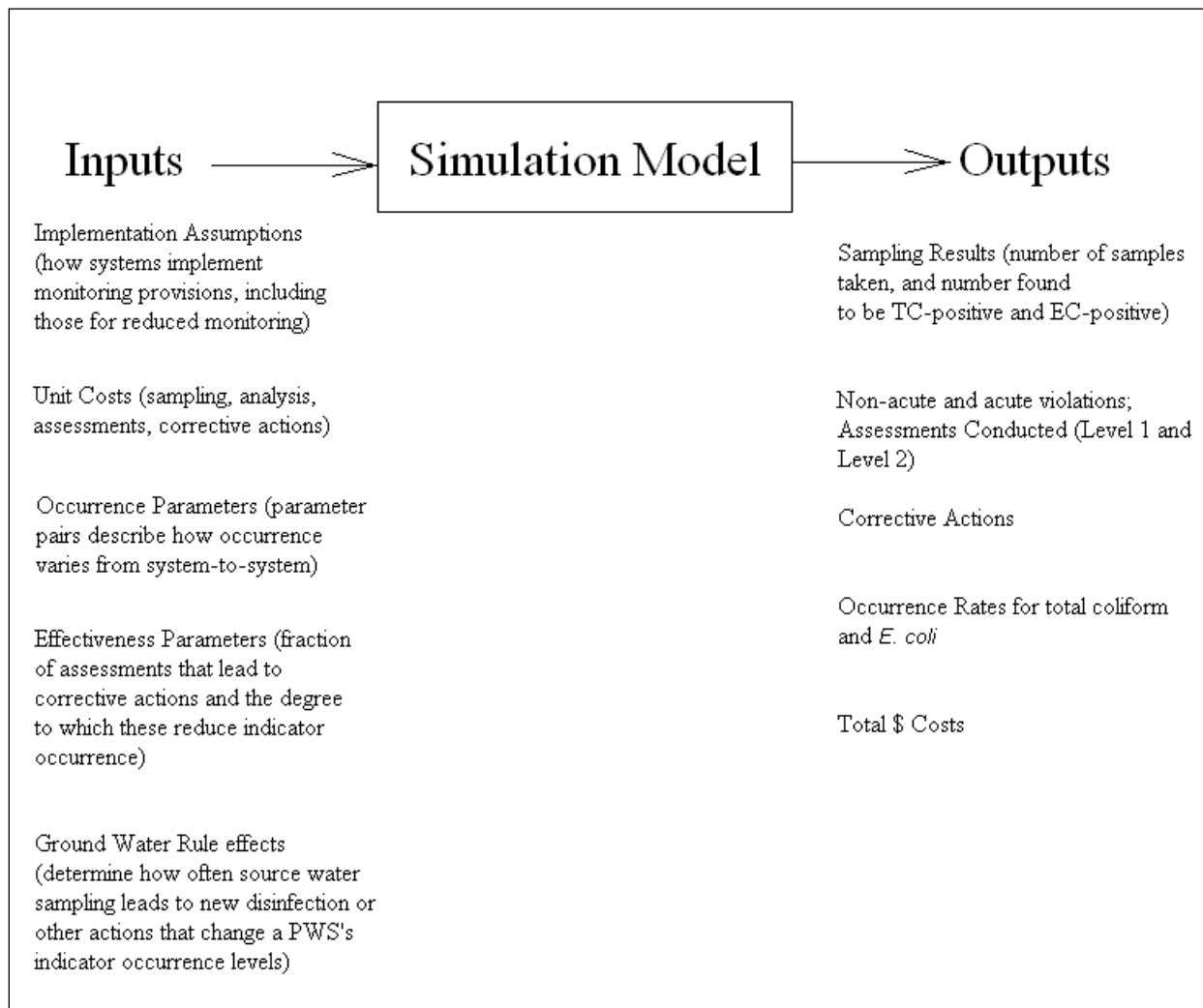
For the immunocompromised, Gerba *et al.* (1996) reviewed the literature and reported that enteric adenovirus and rotavirus are the two waterborne viruses most commonly isolated in the stools of AIDS patients. For patients undergoing bone-marrow transplants, several studies cited by Gerba *et al.* (1996) reported mortality rates greater than 50 percent among patients infected with enteric viruses.

It is anticipated that the requirements of the RTCR will help reduce pathways of entry for fecal contamination and/or waterborne pathogens into the distribution system, thereby reducing risk to both the general population as well as to sensitive subpopulations such as the immunocompromised.

L. Uncertainties in the Benefit and Cost Estimates for the RTCR

A computer simulation model was used to estimate costs and indicators of benefits of the RTCR. Exhibit VI-24 shows that these outputs depend on a number of key model inputs. This section describes analyses that were conducted to understand how uncertainties in these inputs contributed to uncertainty in model outputs.

Exhibit VI-24 Simulation Model, Inputs, and Outputs



1. Inputs and their uncertainties

It is anticipated that the requirements of the RTCR will help reduce pathways of entry for fecal contamination and/or waterborne pathogens into the distribution system, thereby reducing exposure and illness from these contaminants in drinking water. These exposure and illness reductions could not be modeled and estimated quantitatively, due to a lack of a quantitative relationship between indicators and pathogens. Section VI.E.3 of this preamble, *Nonquantifiable benefits*, and chapter 6 of the RTCR EA discuss this issue qualitatively.

Model outputs include two important indicators that are used to qualitatively describe benefits: *E. coli* occurrence in routine total coliform samples and the occurrence of Level 1 and 2 assessments. These outputs were monitored as endpoints in the sensitivity analyses described in this section.

Quantified national cost estimates include costs of required monitoring, assessments, corrective actions, and public notifications. Total costs were monitored as end-points in the sensitivity analyses described in this section.

None of the inputs shown in Exhibit VI-24 is perfectly known, so each has some degree of uncertainty. Some of these inputs are informed directly by data, so their uncertainties are due to limitations of the data. For example, uncertainty about the statistical model used to characterize occurrence is due to the limited numbers of systems and measurements per system in the Six-Year Review 2 dataset. Other inputs are informed by professional judgment, so their uncertainties are expressed in terms of reasonable upper and lower bounds that are, themselves, based on expert judgment. For example, 10 percent of assessments (representing the incremental increase over the 1989 TCR) are expected to result in effective corrective actions, based on professional judgment, with reasonable upper and lower bounds of 20 percent and 5 percent, respectively.

Sensitivity analyses were conducted to assess the degree to which uncertainties about selected inputs contribute to uncertainty in the resulting cost estimates. The analyses focused on the inputs that are listed in Exhibit VI-24. Varying the assumptions about the percentages of corrective actions identified and the effectiveness of those actions has a less than linear effect on outcomes, and the RTCR continues to be less costly than the Alternative option under all scenarios modeled. Exhibits 5.22a and 5.22b of the RTCR EA provide summaries of the driving

model parameters and indicate where in the RTCR EA the full discussion of uncertainty on each parameter is contained.

Not shown in Exhibit VI-24 are some inputs that are very well known. These are inventory data, which include the list of all PWSs affected by the RTCR and, for each system, information on its source water type, disinfection practice, and population served. Although this information is not perfect, any uncertainty is believed to have negligible impact on model outputs. EPA did not conduct sensitivity analyses to evaluate the importance of these small uncertainties.

2. Sensitivity analysis

Default values of the model inputs are considered reasonable best-estimates. Model outputs that are obtained when the inputs are set to these default values are also considered to be reasonable best-estimates. EPA conducted sensitivity analyses to learn how much the outputs might change when individual inputs are changed from their default values. The approach taken was to change each input to some reasonable upper and lower bounds, based on professional judgment.

Many of the uncertainties are expected to impact the model output in a similar fashion for the 1989 TCR, RTCR, and the Alternative option. For example, an increase in a total coliform occurrence tends to increase the total cost and benefit estimates for all of the rule alternatives. Because the benefit and cost analyses focus on net changes among the 1989 TCR, RTCR, and Alternative option, these common sources of uncertainty may tend to cancel out in the net change analyses. Other uncertainties were expected to have stronger influence on net changes among the 1989 TCR, RTCR, and Alternative option because of their unequal influence on the options. For example, assumptions about the effectiveness of corrective actions influences total costs of the RTCR and Alternative option, but not the 1989 TCR option.

Results of the sensitivity analyses (reported in the RTCR EA) showed that the fundamental conclusions of the economic analysis do not change over a wide range of assumptions. Both the RTCR and Alternative option provide benefits as compared to the 1989 TCR. Varying key assumptions has a less than linear effect on outcomes, and the RTCR continues to be less costly than the Alternative option under all scenarios modeled. See section 5.3.3.1 of the RTCR EA for details.

M. Benefit Cost Determination for the RTCR

Pursuant to SDWA section 1412(b)(6)(A), EPA has determined that the benefits of the RTCR justify the costs. In making this determination, EPA considered quantified and nonquantified benefits and costs as well as the other components of the HRRCA outlined in section 1412(b)(3)(C) of the SDWA.

Additionally, EPA used several other techniques to compare benefits and costs including a break-even analysis and a cost effectiveness analysis. EPA developed a break-even analysis to inform the discussion of whether the benefits justify the cost of the regulation. The break-even analysis (see chapter 9 of the RTCR EA) was conducted using two example pathogens responsible for some (unknown) proportion of waterborne illnesses in the United States: shiga toxin-producing *E. coli* O157:H7² (STEC O157:H7) and *Salmonella*. In the break-even analysis, CDC and Economic Research Service (ERS) estimates were used for STEC O157:H7 and *Salmonella* infections, respectively. Valuations of medical cases were developed using the ERS Foodborne Illness Calculator. Chapter 9 of the RTCR EA has a complete discussion of the break even analysis and how costs per case were calculated.

² According to the website of the American Academy of Family Physicians (<http://www.aafp.org/afp/20000401/tips/11.html>), “Shiga toxin-producing *Escherichia coli* is a group of bacteria strains capable of causing significant human disease. The pathogen is transmitted primarily by food and has become an important pathogen in industrialized North America. The subgroup enterohemorrhagic *E. coli* includes the relatively important serotype O157:H7, and more than 100 other non-O157 strains.”

Based on either example pathogen considered in the breakeven analysis, a small number of fatal cases annually would need to be avoided, relative to the CDC’s estimate of cases caused by waterborne pathogens, in order to break even with rule costs. For example, under the RTCR, just two deaths would need to be avoided annually using a three percent discount rate based on consideration of the bacterial pathogen STEC O157:H7. Alternatively, approximately 3,000 or 8,000 non-fatal cases, using the enhanced or traditional benefits valuations approaches³, respectively, would need to be avoided to break even with rule costs. As expected based on its costs, the lower cost of the RTCR relative to the Alternative option means that fewer cases need to be avoided in order to break even. See Exhibit VI-25.

As Exhibit VI-25 shows, approximately 2 deaths would need to be avoided from a *Salmonella* infection for the rule to break even. The estimated number of non-fatal *Salmonella* cases that would need to be avoided to break even is approximately 10,000 or 68,000 cases under the enhanced and traditional benefits valuations approaches, respectively. Given the large number of potential waterborne pathogens shown to occur in PWSs and the relatively low net costs of the RTCR, EPA believes, as discussed in this section and in the RTCR EA, that the RTCR is likely to at least break even. Chapter 9 of the RTCR EA has a complete discussion of the break-even analysis and how costs per case were calculated.

Exhibit VI-25 Estimated Breakeven Threshold for Avoided Cases of *E. coli* O157:H7 and *Salmonella*

Cost of Illness (COI) Methodology	Discount Rate	RTCR	Alternative Option
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³ Both traditional and enhanced cost of illness (COI) approaches count the value of the direct medical costs and of time lost that would be spent working for a wage, but differ in their assessment of the value of time lost that would be spent in nonmarket work (e.g., housework, yardwork, and raising children) and leisure (e.g., recreation, family time, and sleep). They also differ in their valuation of (other) disutility, which encompasses a range of factors of well-being, including both inconvenience and any pain and suffering. A complete discussion of the traditional and enhanced COI approaches can be found in Appendix E of the RTCR EA (USEPA 2012a).

		Non-fatal cases only	Fatal cases only ¹	Non-fatal cases only	Fatal cases only ¹
<i>E. coli</i> O157:H7					
Traditional COI	3%	8,000	1.6	17,000	3.4
	7%	8,000	1.6	18,000	3.6
Enhanced COI	3%	3,000	1.6	6,000	3.4
	7%	3,000	1.6	6,000	3.6
<i>Salmonella</i>					
Traditional COI	3%	68,000	1.6	141,000	3.4
	7%	68,000	1.6	151,000	3.6
Enhanced COI	3%	10,000	1.6	21,000	3.4
	7%	10,000	1.6	23,000	3.6

¹Calculations for fatal cases include the non-fatal COI component for the underlying illness prior to death.

Note: The number of cases needed to reach break-even threshold is calculated by dividing the net change in costs for the RTCR by the average estimated value of avoided cases.

E. coli O157:H7 and *Salmonella* are only two of multiple pathogenic endpoints that could have been used for this analysis. Use of additional pathogenic contaminants in addition to these single endpoints would result in lower threshold values.

Detail may not add due to independent rounding.

The breakeven threshold is higher using a 7% discount rate than a 3% discount rate under the Alternative option. This result is consistent with the costs of the Alternative option being higher using the 7% discount rate, which is caused by the frontloading of costs in the period of analysis, as explained further in Chapter 7 of the RTCR EA (USEPA 2012a).

Cost-effectiveness is another way of examining the benefits and costs of the rule. Exhibit VI-26 shows the cost of the rule per corrective action implemented. The cost-effectiveness analysis, as with the net benefits, is limited because EPA was able to only partially quantify and monetize the benefits of the RTCR. As discussed previously and demonstrated in the RTCR EA, the RTCR achieves the lowest cost per corrective action avoided among the options considered. The incremental cost-effectiveness analysis shows that the RTCR has a lower cost per corrective action than the Alternative option.

Exhibit VI-26 Total Net Annual Cost Per Corrective Action Implemented under RTCR and Alternative Option, Annualized (using three percent and seven percent discount rates) (\$Millions, \$2007)

Regulatory Scenario	3% Discount Rate	7% Discount Rate
RTCR - Net Change	\$ 14.3	\$ 14.2
RTCR - Incremental Number of Corrective Actions (L1 & L2)	616	594

RTCR - Cost Effectiveness Analysis	\$ 0.02	\$ 0.02
Alternative Option - Net Change	\$ 29.6	\$ 31.7
Alternative Option - Incremental Number of Corrective Actions (L1 & L2)	808	819
Alternative Option - Cost Effectiveness Analysis	\$ 0.04	\$ 0.04

Note: Corrective actions include those conducted as a result of either Level 1 or Level 2 assessments. Total rule costs are shown in Exhibit 9.14 of the RTCR EA (USEPA 2012a). Detailed benefits and cost information is provided in Appendices A and C, respectively, of the RTCR EA (USEPA 2012a).

The preferred option for the final rule is the RTCR. The analyses performed as part of the RTCR EA (USEPA 2012a) support the collective judgment and consensus of the advisory committee that the RTCR requirements provide for effective and efficient revisions to the 1989 TCR regulatory requirements. The estimated net cost increase of the RTCR is small (\$14M annually) relative to the 1989 TCR and small compared to the net cost increase of the Alternative option (\$30M – \$32M) relative to the 1989 TCR. In addition, no backsliding in overall risk is predicted.

N. Comments Received in Response to EPA’s Requests for Comment

In the proposal for the RTCR, EPA requested comment on the SAB’s concerns (selection of the RTCR option and measures for tracking long term effectiveness of RTCR), on replacement and maintenance costs for major distribution system appurtenances, on assumptions regarding State use of annual monitoring and annual site visits, and on assumptions regarding the results and effectiveness of Level 1 and Level 2 assessments. This section summarizes the comments EPA received on these issues.

1. SAB’s concerns

Most comments EPA received were in favor of the selection of the RTCR option over the 1989 TCR and the Alternative option. Commenters thought that the additional transition costs associated with the Alternative option did not justify the relatively small increase in benefits and noted that over the long term the benefits for both options were extremely similar. Some

commenters provided EPA with specific input on what kind of data to collect in order to indicate the long term effectiveness of the RTCR. However, most commenters instead emphasized the need for SDWIS to be equipped to record the data, and that necessary changes to SDWIS be made in time for the rule to take effect. EPA remains committed to providing the necessary update to SDWIS before the final rule goes into effect and will continue to work with data users to identify system data collection needs and measures.

2. Costs of major distribution system appurtenances

Most comments supported EPA's decision not to include replacement or maintenance costs of major distribution system appurtenances under the RTCR. However, some commenters expressed concern that some systems, in particular small systems, do not plan for capital expenditures, and therefore these costs should be included. EPA continues to believe, as informed by the TCRDSAC deliberations, that the assessment requirement of the RTCR may help to identify when the useful life of an appurtenance has occurred or maintenance is required, but that these costs should be attributable to regular maintenance and repair, not to the RTCR. Therefore, EPA has not changed this assumption in the EA for the final rule.

3. Annual monitoring and annual site visits

Comments on this subject were mixed. Most commenters thought that the assumption that only states that currently allow annual monitoring and conduct annual site visits would continue to do so under the RTCR was a reasonable one. However, there were some commenters that pointed out that some States that currently do not allow annual monitoring may begin to allow it because of a lack of resources and because of the desire to meet only the minimum aspects of the RTCR. Based on stakeholder input and comments received, EPA continues to believe that

EPA's original assumption is valid, that only States that currently allow annual monitoring and perform annual visits would continue to do so.

4. Effectiveness of assessments

Several commenters agreed that EPA made a reasonable assumption that 10 percent of assessments would lead to corrective action above what is occurring under the 1989 TCR. For those that did not agree the assumption was reasonable, the response was split between those that thought the estimate was too high, and those that thought the estimate was too low. Therefore, EPA has chosen to retain the estimate of 10 percent, which was originally derived with stakeholder input.

Several commenters supported the assumptions regarding the effectiveness of corrective actions. Many of these commenters stated that it would be extremely difficult to determine if these assumptions are accurate or not. Some commenters thought that these assumptions were too optimistic and that little or no benefit would be realized by the use of the assessments and corrective action. In the absence of strong consensus for changing these assumptions, EPA has elected to keep the assumptions in place.

O. Other Comments Received by EPA

In addition to comments received as a result of requests for comment, EPA also received comments on various technical aspects of the EA. Those comments included concerns with the analysis in the following areas: EPA's inability to quantify health benefits, small PWS's possible inability to return to reduced monitoring after being triggered into monthly monitoring, the shift of State resources from public health related activities to tracking and compliance under the RTCR, and estimates about the State burden.

1. Quantifying health benefits

Some commenters expressed concern that EPA is not quantifying benefits. Instead of quantifying the benefits, the RTCR EA examines the benefits in terms of trade-offs between compliance with the 1989 TCR and the other options considered (RTCR and Alternative option). As allowed under and consistent with the HRRCA requirements outlined in section 1412 (b)(3)(C) of the SDWA, EPA used several methods to qualitatively evaluate the benefits of the RTCR and Alternative option. The qualitative evaluation uses both the judgment of EPA as informed by the TCRDSAC deliberations as well as quantitative estimates of changes in total coliform occurrence and counts of systems implementing corrective actions. EPA acknowledges that the predicted benefits of changes in total coliform occurrence and numbers of corrective actions implemented are a function of model assumptions, and EPA recognizes that there is some uncertainty with the assumptions. However, sensitivity analyses showed that the fundamental conclusions of the EA do not change over a wide range of assumptions tested, and that the RTCR provides benefits over the 1989 TCR.

EPA notes that the supporting analyses that formed the foundation of the RTCR EA were reviewed by the SAB. SAB noted in their report that “in general, the Committee was impressed by the work the Agency undertook. The Agency obviously did a great deal of work and put a significant amount of thought into making use of the limited amount of data.” SAB also acknowledged that “the EA represents the best possible analysis given the paucity of available data” (SAB 2010).

2. Return to reduced monitoring

Some commenters stated that PWSs, in particular NCWSs, will never again qualify for quarterly or annual monitoring under the RTCR once they are triggered into increased monthly monitoring. EPA disagrees with this statement. Under the RTCR, NCWSs that are triggered

into monthly monitoring could possibly meet the criteria to once again qualify for (routine) quarterly or (reduced) annual monitoring in as little as one year. Some commenters stated that EPA has underestimated the numbers of systems that will be triggered into monthly monitoring based on existing noncompliance rates, with particular emphasis on systems with monitoring violations.

Consistent with past EPA EA analyses, the occurrence model and cost estimates in the EA do not include estimates for non-compliance with EPA regulatory requirements such as monitoring. In addition, EPA disagrees with many commenters' assumptions that monitoring violation rates will remain the same under the RTCR. EPA believes that the rates of monitoring violations will decrease because of strengthened incentives for systems to monitor and the enhanced consequences of noncompliance. A PWS on quarterly or annual monitoring has a greater incentive under the RTCR to do its monitoring because if it doesn't, it will be triggered into increased monitoring. The 1989 TCR did not include such a requirement. Under the RTCR, if a PWS does not complete its repeat samples, it will be triggered to conduct an assessment. With greater consequences for not completing required sampling, systems will be more likely to complete their monitoring. Thus, EPA believes that rates of monitoring and reporting violations will be lower under the RTCR than they are under the 1989 TCR.

Many commenters had concerns with monitoring violation rates specifically for those systems that are on annual monitoring. EPA believes that the monitoring violation rates for these systems will not be as high as predicted by commenters since one of the requirements to remain on annual monitoring is an annual site visit by the State or a Level 2 assessment. If, at the time of the site visit or the Level 2 assessment, that year's annual samples have not been taken, the State or assessor will have the opportunity to remind the system to take the required samples,

assist the system in taking the sample at that time, or include taking the sample as part of the site visit or assessment.

All triggers to increased monitoring in the RTCR are consistent with EPA's position, as informed by TCRDSAC discussions, that annual monitoring is a privilege for only the most well run systems. Systems that are not able to meet annual monitoring requirements would not be considered among the most well run, and therefore would be triggered into more frequent monitoring.

3. Shift of State resources

Some commenters assert that States will be overwhelmed by the burden of tracking and enforcement activities of RTCR because all small PWSs, especially NCWSs, will be triggered into monthly monitoring under the RTCR and that this will result in a significant increase in violations and tracking and enforcement activities.

In order to address these concerns, EPA made a change from the proposal to this final rule by changing the result of a monitoring violation trigger for systems on annual monitoring. Instead of a monitoring violation triggering a system directly into monthly monitoring, a monitoring violation will now trigger the system in violation to quarterly monitoring. All other triggers (i.e., *E. coli* MCL violation, a Level 2 assessment, a coliform treatment technique violation) continue to move the system to monthly monitoring. This was done to address concerns that too many systems would end up on monthly monitoring and it would be too burdensome for both systems and States. This change did not affect any cost numbers in the EA since the EA does not model non-compliance. See sections III.C.1.b.iv, *Increased monitoring*, and III.C.2.b, *Ground water NCWSs serving ≤ 1,000 people*, of this preamble for a more detailed explanation of this change.

EPA disagrees with any characterization of tracking and enforcement activities as unrelated to public health protection. Tracking and enforcement helps to ensure that systems take their samples, find contamination when it is present, and assess the system and make any necessary corrections improving public health protection. Thus, tracking and enforcement serves an integral role in the protection of public health that RTCR provides.

4. State burden

a. Monitoring and Level 2 assessments. Some commenters expressed concern that States would ultimately bear the costs of conducting monitoring and Level 2 assessments of PWSs. Other commenters indicated that some States already cover the costs of monitoring and assessment-type activities under the 1989 TCR but would no longer be able to do so under the RTCR because the rule would require them to shift their resources to enforcement activities. EPA notes that while States do have the right to choose to cover the costs of conducting monitoring and assessments, the PWSs themselves are ultimately responsible for completing these activities. Neither the 1989 TCR nor the RTCR requires States to conduct monitoring for PWSs. The RTCR allows Level 2 assessments to be conducted by parties approved by the State, including the PWS where appropriate. EPA believes that there are many third parties that can reliably conduct Level 2 assessments, including certified operators, professional engineers, circuit riders and others. This flexibility should allow the State to assure thorough assessments without requiring the State to use its own resources to conduct them.

b. Underestimation. Some commenters said that EPA underestimated the cost for systems and States to read and understand the rule. Others assert that EPA underestimated the cost for annual administration. In calculating the estimates for systems and States to read and understand the rule, EPA looked to estimates prepared for other recent rulemakings, including the Aircraft

Drinking Water Rule (USEPA 2009, 74 FR 53590, October 19, 2009) and the Lead and Copper Rule Short-Term Revisions (USEPA 2007, 72 FR 57782, October 10, 2007). EPA then considered the rule requirements in comparison to the 1989 TCR, given that systems and States are well acquainted with the 1989 rule. The 4-hour figure is a national average, and may vary due to individual system complexity. EPA continues to believe that the estimated number of hours to read and understand the RTCR is logical.

VII. Statutory and Executive Order Review

A. Executive Order 12866: Regulatory Planning and Review and Executive Order

13563:Improving Regulation and Regulatory Review

Under Executive Order 12866 (58 FR 51735, October 4, 1993), this action is a significant regulatory action. Accordingly, EPA submitted this action to the Office of Management and Budget (OMB) for review under Executive Orders 12866 and 13563 (76 FR 3821, January 21, 2011) and any changes made in response to OMB recommendations have been documented in the docket for this action.

EPA estimates that the RTCR will have an overall annual impact on PWSs of \$14 M and that the impact on small entities (PWSs serving 10,000 people or fewer) will be \$10.0M - \$10.3M annualized at three and seven percent discount rates, respectively. These impacts are described in sections VI, *Economic Analysis (Health Risk Reduction and Cost Analysis)*, and VII.C, *Regulatory Flexibility Act (RFA)*, of this preamble, respectively, and in the analysis that EPA prepared of the potential costs and benefits of this action, contained in the RTCR EA.

B. Paperwork Reduction Act

The information collection requirements in this rule will be submitted for approval to the OMB under the Paperwork Reduction Act, 44 U.S.C. 3501 et seq. The information collection requirements are not enforceable until OMB approves them.

The information collected as a result of this rule will allow States/primacy agencies and EPA to determine appropriate requirements for specific systems and evaluate compliance with the proposed RTCR. Burden is defined at 5 CFR 1320.3(b) and means the total time, effort, and financial resources required to generate, maintain, retain, disclose, or provide information to or for a Federal agency. The burden for this final rule includes the time needed to conduct the following State and PWS activities:

State activities:

- Read and understand the rule;
- Mobilize (including primacy application), plan, and implement;
- Train PWS and consultant staff;
- Track compliance;
- Analyze and review PWS data;
- Review sample siting plans and recommend any revisions to PWSs;
- Make determinations concerning PWS monitoring requirements;
- Respond to PWSs that have positive samples;
- Recordkeeping;
- Review completed assessment forms and consult with the PWS about the assessment report;
- Review and coordinate with PWSs to determine optimal corrective actions to be implemented; and
- Provide consultation, review PN certifications, and file reports of violations.

PWS activities:

- Read and understand the rule;
- Planning and mobilization activities;
- Revise existing sample siting plans to identify sampling locations and collection schedules that are representative of water throughout the distribution system;
- Conduct routine, additional routine, and repeat monitoring, and report the results as required;
- Complete a Level 1 assessment if the PWS experiences a Level 1 trigger, and submit a form to the State to identify sanitary defects detected, corrective actions completed, and a timetable for any corrective actions not already completed;
- Complete a Level 2 assessment if the PWS experiences a Level 2 trigger, and submit a form to the State to identify sanitary defects detected, corrective actions completed, and a timetable for any corrective actions not already completed;
- Correct sanitary defects found through the performance of Level 1 or Level 2 assessments and report on completion of corrective actions as required;
- Develop and distribute Tier 1 public notices when *E. coli* MCL violations occur;
- Develop and distribute Tier 2 public notices when the PWSs fail to take corrective action; and
- Develop and distribute Tier 3 public notices when the PWSs fail to comply with the monitoring requirements or with mandatory reporting of required information within the specified timeframe.

For the first three years after publication of the RTCR in the FR, the major information requirements apply to 154,894 respondents. The total incremental burden associated with the change in moving from the information requirements of the 1989 TCR to those in the RTCR

over the three years covered by the ICR is 2,518,578 hours, for an average of 839,526 hours per year. The total incremental cost over the three-year clearance period is \$71.3M, for an average of \$23.8M per year (simple average over three years). (Note that this is higher than the annualized costs for the RTCR because in the EA, the up-front costs that occur in the first three years, as well as future costs, are annualized over a 25-year time horizon.) The average burden per response (i.e., the amount of time needed for each activity that requires a collection of information) is 5.4 hours; the average cost per response is \$153. The collection requirements are mandatory under SDWA section 1445(a)(1). Detail on the calculation of the RTCR’s information collection burden and costs can be found in the ICR for the Revised Total Coliform Rule (USEPA 2012c) and chapter 8 of the EA (USEPA 2012a). A summary of the burden and costs of the collection is presented in Exhibit VII-1.

Exhibit VII-1 Average Annual Net Change Burden and Costs for the RTCR ICR

Respondent Type	Annual Burden Hours	Cost				Annual Responses
		Annual Labor Cost	Annual Operation & Maintenance (O&M) Cost	Annual Capital Cost	Total Annual Cost	
PWSs	747,848	\$20,171,639	\$-	\$-	\$20,171,639	103,225
States and Territories	91,678	\$3,595,421	\$-	\$-	\$3,595,421	51,669
Total	839,526	\$23,767,060	\$-	\$-	\$23,767,060	154,894

Notes: Detail may not add exactly to total due to independent rounding.
 “Annual Burden Hours” reflects an annual average for all system sizes over the 3-year ICR period.
 Source: ICR for the Revised Total Coliform Rule (USEPA 2012c)

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The OMB control numbers for EPA's regulations in 40 CFR are listed in 40 CFR part 9. When this ICR is approved by OMB, the Agency will publish a technical amendment to 40 CFR part 9 in the FR

to display the OMB control number for the approved information collection requirements contained in this final rule.

C. Regulatory Flexibility Act (RFA)

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

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

For purposes of assessing the impacts of the RTCR on small entities, EPA considered small entities to be PWSs serving 10,000 or fewer people. This is the cut-off level specified by Congress in the 1996 Amendments to the SDWA for small system flexibility provisions. As required by the RFA, EPA proposed using this alternative definition in the FR (63 FR 7620, February 13, 1998), requested public comment, consulted with the SBA, and finalized the

alternative definition in the Agency's CCR regulation (63 FR 44524, August 19, 1998). As stated in that Final Rule, the alternative definition would be applied for all future drinking water regulations.

After considering the economic impacts of the RTCR on small entities, I certify that this action will not have a significant economic impact on a substantial number of small entities. The small entities directly regulated by this rule are small PWSs serving 10,000 or fewer people. These include small CWSs, NTNCWSs, and TNCWSs, entities such as municipal water systems (publicly and privately owned), and privately-owned PWSs and for-profit businesses where provision of water may be ancillary, such as mobile home parks, day care centers, churches, schools and homeowner associations. We have determined that only 61 of 150,672 small systems (0.04%) will experience an impact of more than 1% of revenues, and that none of the small systems will experience an impact of 3% or greater of revenue. This information is described further in chapter 8 of the RTCR EA.

Although this final rule will not have a significant economic impact on a substantial number of small entities, EPA nonetheless has tried to reduce the impact of this rule on small PWSs. Provisions in the RTCR that result in reduced costs for many small entities include:

- Reduced routine monitoring for qualifying PWSs serving 1,000 or fewer people.
- Reduced number of repeat samples required for systems serving 1,000 or fewer people.
- Reduced additional routine monitoring for PWSs serving 4,100 or fewer people.
- Reduced PN requirements for all systems, including small systems.

EPA also conducted outreach to small entities and convened a Small Business Advocacy Review Panel to obtain advice and recommendations of representatives of the small entities that potentially would be subject to this rule's requirements. For a description of the Small Business

Advocacy Review Panel and stakeholder recommendations, please see section VII.C of the preamble to the proposed RTCR, *Regulatory Flexibility Act (RFA)*.

D. Unfunded Mandates Reform Act (UMRA)

This rule does not contain a Federal mandate under the provisions of Title II of the Unfunded Mandates Reform Act of 1995 (UMRA), 2 U.S.C. 1531-1538 that may result in expenditures to State, local, and Tribal governments, in the aggregate, or to the private sector, of \$100M or more in any one year. Expenditures associated with compliance, defined as the incremental costs beyond the 1989 TCR, will not surpass \$100M in the aggregate in any year. Thus, this rule is not subject to the requirements of sections 202 and 205 of UMRA.

The RTCR is also not subject to the requirements of section 203 of UMRA because it contains no regulatory requirements that might significantly or uniquely affect small governments. Costs to small entities are generally not significant, as described previously in section VII.C of this preamble, *Regulatory Flexibility Act (RFA)*, and are detailed in the RTCR EA. The regulatory requirements of the final RTCR are not unique to small governments, as they apply to all PWSs regardless of size.

E. Executive Order 13132: Federalism

This action does not have Federalism implications. It will not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government as specified in Executive Order 13132. The net change in cost for State, local, and Tribal governments in the aggregate is estimated to be approximately \$0.2M and \$0.4M at three percent and seven percent discount rates, respectively. Thus, Executive Order 13132 does not apply to this final rule.

Although section 6 of Executive Order 13132 does not apply to the RTCR, EPA conducted a Federalism Consultation, consistent with Executive Order 13132, in July 2008. The consultation included a stakeholder meeting where EPA requested comments on the impacts of the potential revisions to the 1989 TCR with respect to State, county and local governments. EPA did not receive any comments in response to this consultation. In addition, the advisory committee included representatives of State, local and Tribal governments, and through this process EPA consulted with State, local, and Tribal government representatives to ensure that their views were considered when the AIP recommendations for the proposed RTCR were developed. EPA also included representatives from four states on its workgroup for developing the proposed RTCR.

In the spirit of Executive Order 13132 and consistent with EPA policy to promote communications between EPA and State and local governments, EPA specifically solicited comment on the proposed action from State and local officials. Some States were concerned with the burden of implementing the rule, especially those States that have a high proportion of NCWSs. Under this rule, expenditures for assessments and corrective actions and increased monitoring are targeted to the fraction of PWSs that are most vulnerable to pathways for contamination of the distribution system, thereby minimizing the burden for the majority of PWSs and for States implementing the rule. As described in sections III.E.2, *Assessment*, and III.C.1.b.iv, *Increased monitoring*, of this preamble, EPA is also providing flexibility on how the PWSs and States conduct and track assessments, and by changing the consequence for systems on annual monitoring that have RTCR monitoring violations (i.e., increase to quarterly monitoring instead of monthly monitoring). EPA also has plans to update SDWIS to maximize its efficiency in support of rule implementation. These actions should address many of the State concerns about burden.

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

This action does not have tribal implications, as specified in Executive Order 13175 (65 FR 67249, November 9, 2000). EPA consulted with Tribes throughout the development of the RTCR (as described in this section) and no issues that were particular to Tribal entities were identified.

Although Executive Order 13175 does not apply to this action, EPA consulted with Tribal officials in developing this action. EPA consulted with Tribal governments through the EPA American Indian Environmental Office; included a representative of the Native American Water Association on the advisory committee who helped develop and signed the AIP on recommendations on the proposed rule; and addressed Tribal concerns throughout the regulatory development process, as appropriate. The consultation included participation in three Tribal conference calls (EPA regional Tribal call (February 2008), National Indian Workgroup call (March 2008), and National Tribal Water Conference (March 2008)). EPA requested comments on the 1989 TCR, requested suggestions for 1989 TCR revisions (March 2008), and presented possible revisions to the 1989 TCR to the National Tribal Council (April 2008). In addition, the advisory committee included a representative from the Native American Water Association who represented Tribal entities, and through this process EPA ensured that Tribal views were considered when the AIP recommendations for the proposed RTCR were developed. None of these consultations identified issues that were particular to Tribal entities. EPA also specifically solicited additional comment on the proposed rule from Tribal officials, and no additional issues were identified. As a result of the Tribal consultations and other Tribal outreach, EPA has determined that the RTCR is not anticipated to have a negative impact on Tribal systems. Thus, Executive Order 13175 does not apply to this action.

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

The RTCR is not subject to Executive Order 13045 (62 FR 19885, April 23, 1997) because it is not economically significant as defined in Executive Order 12866, and because the Agency does not believe the environmental health or safety risks addressed by this action present a disproportionate risk to children. This action's health and risk assessments regarding children are contained in section VI.K.1 of this preamble, *Risk to children, pregnant women, and the elderly*, and in the RTCR EA. EPA expects that the RTCR would provide additional protection to both children and adults who consume drinking water supplied from PWSs. EPA also believes the benefits of this rule, including reduced health risk, accrue more to children because young children are more susceptible than adults to some waterborne illnesses. For example, the risk of mortality resulting from diarrhea is often greatest in the very young and elderly (Rose 1997; Gerba *et al.* 1996), and viral and bacterial illnesses often disproportionately affect children. Any overall benefits of the rule would reduce this mortality risk for children.

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

This rule is not a "significant energy action" as defined in Executive Order 13211 (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. Additionally, none of the requirements of this rule involve the installation of treatment or other components that use a measurable amount of energy.

I. National Technology Transfer and Advancement Act

Section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law No. 104-113, 12(d) (15 U.S.C. 272 note), directs EPA to use voluntary consensus

standards in its regulatory activities unless to do so would be inconsistent with applicable law or otherwise impractical. Voluntary consensus standards are technical standards (e.g., materials specifications, test methods, sampling procedures, and business practices) that are developed or adopted by voluntary consensus standards bodies. NTTAA directs EPA to provide Congress, through OMB, explanations when EPA decides not to use available and applicable voluntary consensus standards.

This rule involves technical voluntary consensus standards. As in the 1989 TCR, under the provisions of the RTCR water systems are required to use several analytical methods to monitor for total coliforms and/or *E. coli* as they are described in *Standard Methods for the Examination of Water and Wastewater*, 20th and 21st editions (Clesceri *et al.* 1998; Eaton *et al.* 2005).

Methods included in *Standard Methods* are voluntary consensus standards. The 1989 TCR and RTCR include the same 11 methods that can be used to test for total coliforms. Four of the 11 are voluntary consensus methods described in *Standard Methods*.

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

Executive Order 12898 (59 FR 7629, February 16, 1994) establishes federal executive policy on environmental justice. Its main provision directs federal agencies, to the greatest extent practicable and permitted by law, to make environmental justice part of their mission. Agencies must do this by identifying and addressing, as appropriate, any disproportionately high and adverse human health or environmental effects of their programs, policies, and activities on minority populations and low-income populations in the US.

EPA has determined that this action will not have disproportionately high and adverse human health or environmental effects on minority or low-income populations because it increases the

level of environmental protection for all affected populations without having any disproportionately high and adverse human health or environmental effects on any population, including any minority or low-income population. The RTCR applies uniformly to all PWSs and consequently provides health protection equally to all income and minority groups served by PWSs. The RTCR 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. To the extent that contaminants in drinking water might be disproportionately high among minority or low-income populations (which is unknown), the RTCR contributes toward removing those differences by assuring that all public water systems meet drinking water standards and take appropriate corrective action whenever appropriate. Thus, the RTCR meets the intent of the Federal policy requiring incorporation of environmental justice into Federal agency missions.

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

In accordance with section 1412(d) and (e) of the SDWA, EPA consulted with the SAB, the NDWAC, and the Secretary of the US Department of Health and Human Services on the RTCR.

EPA met with the Drinking Water Committee (DWC) of the SAB to discuss the proposed RTCR on May 20, 2009 (teleconference) and June 9 and 10, 2009 (Washington, DC). The SAB DWC review focused on (1) the data sources used to estimate baseline total coliform and *E. coli* occurrence, public water system profile, and sensitive subpopulations in the US; (2) the occurrence analysis used to inform the benefits analysis; (3) the qualitative analysis used to assess the reduction in risk due to implementation of the rule requirements; and (4) analysis of the engineering costs and costs to States resulting from implementation of the revisions.

Overall, the SAB DWC supported EPA's analysis. SAB members commended EPA for making use of the best available data to assess the impacts of the proposed rule. The SAB DWC supported the decision by EPA not to quantify public health benefits, acknowledging that EPA had insufficient data to do so. However, they noted in their analysis of the EA that they are not generally supportive of decreased monitoring, and that overall, the Alternative option appears to address and protect public health sooner in time than the AIP proposed implementation. The SAB DWC recommended that EPA clarify rationales for assumptions; expand explanations of sensitivity analyses that were included; provide further justification in those areas in which sensitivity analyses were not conducted; and collect data after promulgation of the rule to allow EPA to better understand the public health impacts of the RTCR.

In response to the SAB DWC recommendations, EPA conducted sensitivity analyses to explore a wider range of assumptions regarding the percentage of assessments leading to corrective actions and to demonstrate that using an annual average for occurrence provided results comparable to varying the occurrence based on the season. EPA also added an exhibit in the EA that summarizes all significant model parameters and assumptions, their influence on variability and uncertainty, and their most likely effect on benefits or costs. The added exhibits and expanded and clarified text can be found in the RTCR EA. A copy of the SAB report (SAB 2010) is available in the docket for this rule.

EPA consulted with NDWAC on May 28, 2009, in Seattle, Washington, to discuss the proposed RTCR. NDWAC members expressed concern that a rule based on the AIP sounds complicated and recommended that EPA provide the utilities and States with tools to help them understand the revised rule provisions and to assist with providing public education. In response to NDWAC's concern, EPA requested comment on whether the proposed RTCR would result in requirements that would be easier to implement compared to the 1989 TCR.

EPA heard from commenters that the RTCR will be difficult to implement in States that have a lot of small NCWSs, especially the reduced and increased monitoring provisions. To address this concern, EPA provided flexibility to States to help them implement, and to PWSs to help them comply, with the monitoring provisions of the RTCR. States are given the flexibility to not count monitoring violations towards eligibility for a TNCWS to remain on quarterly monitoring or to return to quarterly monitoring as long as the system collects the make-up sample by the end of the next monitoring period. EPA also changed the consequence of having one RTCR monitoring violation for systems on annual monitoring. Instead of having to go to monthly monitoring, the system now moves to quarterly monitoring. See section III.C.2.b of this preamble, *Ground water NCWSs serving $\leq 1,000$ people*, for more details.

NDWAC members also suggested that EPA request comment on the costs and benefits of reduced monitoring. Specifically, NDWAC expressed concern that a reduction in the number of certain samples taken (such as the reduction in the number of repeat and additional routine samples for some small systems) could lessen the opportunity for systems to identify violations. Thus, EPA requested comment on the cost and benefit of reduced monitoring.

EPA received comment that expressed concern that a reduction in the number of additional routine samples reduces the likelihood of detecting both total coliforms and *E. coli*. EPA and the advisory committee recognized that a reduction in the number of samples taken could also mean a reduction in the number of positive samples found. However, EPA and the advisory committee concluded that the new assessment and corrective action provisions of the RTCR lead to a rule that is more protective of public health and to improvement in water quality despite the reductions in the number of samples taken. See section III.C.2.b of this preamble, *Ground water NCWSs serving $\leq 1,000$ people*, for more details

A few NDWAC members stated that they would like to provide EPA with additional advice on PN. To follow up on this request, EPA met with several NDWAC members on July 1, 2009, to review and discuss the 1989 TCR PN requirements, the advisory committee's recommendations on revisions to the PN requirements, and to obtain feedback from NDWAC members. EPA considered the recommendations from NDWAC in developing the PN requirements and requested comment on these issues in the preamble to the proposed RTCR.

EPA consulted with NDWAC again on July 21, 2011, to discuss the draft final rule and comments received on the proposed RTCR, specifically regarding those areas where NDWAC made recommendations in the March and July 2009 consultations. The NDWAC members recommended that in finalizing the RTCR, EPA follow the recommendations of the TCRDSAC.

EPA completed its consultations with the US Department of Health and Human Services on October 5, 2009, and August 8, 2011, as required by SDWA section 1412(d). EPA provided an informational briefing to the Center for Food Safety office of the Food and Drug Administration and representatives from the Office of the Assistant Secretary for Health and the Assistant Secretary for Planning and Evaluation at the Department of Health and Human Services. No substantive comments were received as a result of the briefing and consultation.

L. Considerations of Impacts on Sensitive Subpopulations as Required by Section

1412(b)(3)(C)(i)(V) of the 1996 Amendments of SDWA

As required by Section 1412(b)(3)(C)(i)(V) of the SDWA, EPA sought public comment regarding the effects of contamination associated with the proposed RTCR on the general population and sensitive subpopulations. Sensitive subpopulations include “infants, children, pregnant women, the elderly, individuals with a history of serious illness, or other subpopulations that are identified as likely to be at greater risk of adverse health effects due to

exposure to contaminants in drinking water than the general population” (SDWA section 1412(b)(3)(C)(i)(V), 42 U.S.C 300g-1(b)(3)(C)(i)(V)).

Pregnant and lactating women may be at an increased risk from pathogens as well as act as a source of infection for newborns. 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 continued increase in Human Immunodeficiency Virus/AIDS, the aging population, and the escalation in organ and tissue transplantations. Immunocompromised individuals are more susceptible to severe and invasive infection. These infections are particularly difficult to treat and can result in a significantly higher mortality than in immunocompetent persons.

It is anticipated that the requirements of the RTCR will help reduce pathways of entry for fecal contamination and/or waterborne pathogens into the distribution system, thereby reducing exposure and risk from these contaminants in drinking water to the entire general population. The RTCR seeks to provide a similar level of drinking water protection to all groups including sensitive subpopulations, thus meeting the intent of this Federal policy. See also section VI.K of this preamble, *Effects of Fecal Contamination and/or Waterborne Pathogens on the General Population and Sensitive Subpopulations*, for a more detailed discussion of this topic.

M. Effect of Compliance with the RTCR on the Technical, Financial, and Managerial Capacity of Public Water Systems

Section 1420(d)(3) of the SDWA, as amended, requires that, in promulgating an NPDWR, the Administrator shall include an analysis of the likely effect of compliance with the regulation on the technical, managerial, and financial (TMF) capacity of PWSs. The following analysis fulfills this statutory obligation by identifying the incremental impact that the RTCR will have on the TMF capacity of regulated water systems. Analyses presented in this document reflect only the impact of new or revised requirements, as established by the RTCR; the impacts of previously established requirements on system capacity are not considered.

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

Technical Capacity	
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?
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 and storage facilities, and distribution systems? What is the infrastructure's life expectancy? Does the system have a capital improvement plan?
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 O&M program?
Managerial Capacity	
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 (i.e., to conduct implementation, monitor for <i>E. coli</i>)? 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	
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?

EPA looked at the major requirements of the RTCR that may affect the TMF capacity of PWSs. These requirements include: sample siting plan revision, monitoring, assessments, corrective actions, and PNs. Another factor that may affect the TMF capacity is the need for PWS personnel to familiarize themselves with the RTCR requirements. EPA developed a scoring system to analyze the impact of complying with these requirements on the TMF capacity of PWSs. A detailed discussion of EPA's analysis is presented in chapter 8.14 of the RTCR EA (USEPA 2012a).

The RTCR will apply to all PWSs and may affect 51,972 CWSs, 18,729 NTNCWSs, and 84,136 TNCWSs – 154,837 systems in all. While some systems may require increased TMF capacity to comply with the new RTCR requirements, or will need to tailor their compliance approaches to match their capacities, most systems will not.

Small systems will likely face only a small challenge to their technical and managerial capacity as a result of efforts to familiarize themselves with the monitoring requirements of the RTCR. Routine and repeat monitoring requirements under the RTCR are essentially the same as under the 1989 TCR, with more explicit criteria to qualify for reduced monitoring. Therefore, understanding the RTCR monitoring requirements is not expected to pose many new technical or managerial capacity issues for small systems.

Small system technical and managerial capacity may be affected by the assessment requirements of the RTCR. Performing assessments may require the system to increase staffing levels in addition to providing training to ensure that system staff understand how those assessments are to be performed. 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 some corrective actions may consist of a large, one-time capital expenditure to resolve the problem.

Large systems will likely not face any significant challenge to their technical and managerial capacity as a result of efforts to familiarize themselves with the RTCR. Most large systems are familiar with the 1989 TCR and there are no changes in the basic monitoring requirements for large systems under the RTCR. They are therefore assumed to already have the TMF capacity in place for the RTCR.

Only large systems performing assessments and corrective actions would be expected to face a significant challenge meeting the TMF capacity requirements. However, this requirement is only necessary when monitoring reveals potential problems, and this is not expected to occur significantly in large systems above that experienced under the 1989 TCR. Many large systems already have the TMF capacity to conduct assessments and corrective actions if they are needed. These systems will be affected less significantly than smaller systems that have to implement corrective actions because it is recognized that they are typically already implementing similar assessments and corrective actions when a routine monitoring sample tests positive for fecal indicators under the 1989 TCR.

N. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 et seq., as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the US. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the US prior to publication of the rule in the FR. A Major rule cannot take effect until 60 days after it is published in the FR. This action is not a "major rule" as defined by 5 U.S.C. 804(2). This rule will be effective **[INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]**.

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List of Subjects

40 CFR Part 141

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

40 CFR Part 142

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

Dated: _____

Lisa P. Jackson,

Administrator.

For the reasons set forth in the preamble, Title 40 chapter 1 of the Code of Federal Regulations is amended as follows:

PART 141 - NATIONAL PRIMARY DRINKING WATER REGULATIONS

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

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

2. Section 141.2 is amended by adding, in alphabetical order, definitions for “clean compliance history“, “Level 1 assessment“, “Level 2 assessment“, “sanitary defect“, and “seasonal system“ to read as follows:

§ 141.2 Definitions.

Clean compliance history is, for the purposes of subpart Y, a record of no MCL violations under § 141.63; no monitoring violations under § 141.21 or subpart Y; and no coliform treatment technique trigger exceedances or treatment technique violations under subpart Y.

Level 1 assessment is an evaluation to identify the possible presence of sanitary defects, defects in distribution system coliform monitoring practices, and (when possible) the likely reason that the system triggered the assessment. It is conducted by the system operator or owner. Minimum elements include review and identification of atypical events that could affect distributed water quality or indicate that distributed water quality was impaired; changes in distribution system maintenance and operation that could affect distributed water quality (including water storage); source and treatment considerations that bear on distributed water quality, where appropriate

(e.g., whether a ground water system is disinfected); existing water quality monitoring data; and inadequacies in sample sites, sampling protocol, and sample processing. The system must conduct the assessment consistent with any State directives that tailor specific assessment elements with respect to the size and type of the system and the size, type, and characteristics of the distribution system.

Level 2 assessment is an evaluation to identify the possible presence of sanitary defects, defects in distribution system coliform monitoring practices, and (when possible) the likely reason that the system triggered the assessment. A Level 2 assessment provides a more detailed examination of the system (including the system's monitoring and operational practices) than does a Level 1 assessment through the use of more comprehensive investigation and review of available information, additional internal and external resources, and other relevant practices. It is conducted by an individual approved by the State, which may include the system operator.

Minimum elements include review and identification of atypical events that could affect distributed water quality or indicate that distributed water quality was impaired; changes in distribution system maintenance and operation that could affect distributed water quality (including water storage); source and treatment considerations that bear on distributed water quality, where appropriate (e.g., whether a ground water system is disinfected); existing water quality monitoring data; and inadequacies in sample sites, sampling protocol, and sample processing. The system must conduct the assessment consistent with any State directives that tailor specific assessment elements with respect to the size and type of the system and the size, type, and characteristics of the distribution system. The system must comply with any expedited actions or additional actions required by the State in the case of an *E. coli* MCL violation.

Sanitary defect is a defect that could provide a pathway of entry for microbial contamination into the distribution system or that is indicative of a failure or imminent failure in a barrier that is already in place.

Seasonal system is a non-community water system that is not operated as a public water system on a year-round basis and starts up and shuts down at the beginning and end of each operating season.

3. Section 141.4 is revised to read as follows:

§ 141.4 Variances and exemptions.

(a) Variances or exemptions from certain provisions of these regulations may be granted pursuant to sections 1415 and 1416 of the Act and subpart K of part 142 of this chapter (for small system variances) by the entity with primary enforcement responsibility, except that variances or exemptions from the MCLs for total coliforms and *E. coli* and variances from any of the treatment technique requirements of subpart H of this part may not be granted.

(b) EPA has stayed the effective date of this section relating to the total coliform MCL of §141.63(a) for systems that demonstrate to the State that the violation of the total coliform MCL is due to a persistent growth of total coliforms in the distribution system rather than fecal or pathogenic contamination, a treatment lapse or deficiency, or a problem in the operation or maintenance of the distribution system. This is stayed until March 31, 2016, at which time the total coliform MCL is no longer effective.

NOTE TO PARAGRAPH (a): As provided in § 142.304(a), small system variances are not available for rules addressing microbial contaminants, which would include subparts H, P, S, T, W, and Y of this part.

4. Section 141.21 is amended by adding paragraph (h) to read as follows:

§ 141.21 Coliform sampling.

(h) The provisions of paragraphs (a) and (d) are applicable until March 31, 2016. The provisions of paragraphs (b), (c), (e), (f), and (g) are applicable until all required repeat monitoring under paragraph (b) and fecal coliform or *E. coli* testing under paragraph (e) that was initiated by a total coliform-positive sample taken before April 1, 2016 is completed, as well as analytical method, reporting, recordkeeping, public notification, and consumer confidence report requirements associated with that monitoring and testing. Beginning April 1, 2016, the provisions of subpart Y of this part are applicable, with systems required to begin regular monitoring at the same frequency as the system-specific frequency required on March 31, 2016.

5. Section 141.52 is revised to read as follows:

§ 141.52 Maximum contaminant level goals for microbiological contaminants.

(a) MCLGs for the following contaminants are as indicated:

Contaminant	MCLG
(1) <i>Giardia lamblia</i>	zero
(2) Viruses	zero
(3) <i>Legionella</i>	zero

(4) Total coliforms (including fecal.....zero
coliforms and *Escherichia coli*)

(5) *Cryptosporidium* zero

(6) *Escherichia coli* (*E. coli*).....zero

(b) The MCLG identified in paragraph (a)(4) of this section is applicable until March 31, 2016.

The MCLG identified in paragraph (a)(6) of this section is applicable beginning April 1, 2016.

6. Section 141.63 is revised to read as follows:

§ 141.63 Maximum contaminant levels (MCLs) for microbiological contaminants.

(a) Until March 31, 2016, the total coliform MCL is based on the presence or absence of total coliforms in a sample, rather than coliform density.

(1) For a system that collects at least 40 samples per month, if no more than 5.0 percent of the samples collected during a month are total coliform-positive, the system is in compliance with the MCL for total coliforms.

(2) For a system that collects fewer than 40 samples per month, if no more than one sample collected during a month is total coliform-positive, the system is in compliance with the MCL for total coliforms.

(b) Until March 31, 2016, any fecal coliform-positive repeat sample or *E. coli*-positive repeat sample, or any total coliform-positive repeat sample following a fecal coliform-positive or *E. coli*-positive routine sample, constitutes a violation of the MCL for total coliforms. For purposes of the public notification requirements in subpart Q of this part, this is a violation that may pose an acute risk to health.

(c) Beginning April 1, 2016, a system is in compliance with the MCL for *E. coli* for samples taken under the provisions of subpart Y of this part unless any of the conditions identified in paragraphs (c)(1) through (c)(4) of this section occur. For purposes of the public notification requirements in subpart Q of this part, violation of the MCL may pose an acute risk to health.

(1) The system has an *E. coli*-positive repeat sample following a total coliform-positive routine sample.

(2) The system has a total coliform-positive repeat sample following an *E. coli*-positive routine sample.

(3) The system fails to take all required repeat samples following an *E. coli*-positive routine sample.

(4) The system fails to test for *E. coli* when any repeat sample tests positive for total coliform.

(d) Until March 31, 2016, a public water system must determine compliance with the MCL for total coliforms in paragraphs (a) and (b) of this section for each month in which it is required to monitor for total coliforms. Beginning April 1, 2016, a public water system must determine compliance with the MCL for *E. coli* in paragraph (c) of this section for each month in which it is required to monitor for total coliforms.

(e) The Administrator, pursuant to section 1412 of the Act, hereby identifies the following as the best technology, treatment techniques, or other means available for achieving compliance with the maximum contaminant level for total coliforms in paragraphs (a) and (b) of this section and for achieving compliance with the maximum contaminant level for *E. coli* in paragraph (c) of this section:

(1) Protection of wells from fecal contamination by appropriate placement and construction;

(2) Maintenance of a disinfectant residual throughout the distribution system;

(3) Proper maintenance of the distribution system including appropriate pipe replacement and repair procedures, main flushing programs, proper operation and maintenance of storage tanks and reservoirs, cross connection control, and continual maintenance of positive water pressure in all parts of the distribution system;

(4) Filtration and/or disinfection of surface water, as described in subparts H, P, T, and W of this part, or disinfection of ground water, as described in subpart S of this part, using strong oxidants such as chlorine, chlorine dioxide, or ozone; and

(5) For systems using ground water, compliance with the requirements of an EPA-approved State Wellhead Protection Program developed and implemented under section 1428 of the SDWA.

(f) The Administrator, pursuant to section 1412 of the Act, hereby identifies the technology, treatment techniques, or other means available identified in paragraph (e) of this section as affordable technology, treatment techniques, or other means available to systems serving 10,000 or fewer people for achieving compliance with the maximum contaminant level for total coliforms in paragraphs (a) and (b) of this section and for achieving compliance with the maximum contaminant level for *E. coli* in paragraph (c) of this section.

7. Section 141.71 is amended by revising paragraph (b)(5) to read as follows:

§ 141.71 Criteria for avoiding filtration.

(b) ***

(5) The public water system must comply with the maximum contaminant level (MCL) for total coliforms in § 141.63(a) and (b) and the MCL for *E. coli* in § 141.63(c) at least 11 months of the 12 previous months that the system served water to the public, on an ongoing basis, unless the

State determines that failure to meet this requirement was not caused by a deficiency in treatment of the source water.

8. Section 141.74 is amended by revising paragraphs (b)(6)(i) and (c)(3)(i) to read as follows:

§ 141.74 Analytical and monitoring requirements.

(b) ***

(6)(i) Until March 31, 2016, the residual disinfectant concentration must be measured at least at the same points in the distribution system and at the same time as total coliforms are sampled, as specified in § 141.21. Beginning April 1, 2016, the residual disinfectant concentration must be measured at least at the same points in the distribution system and at the same time as total coliforms are sampled, as specified in §§ 141.854 through 141.858. The State may allow a public water system which uses both a surface water source or a ground water source under direct influence of surface water, and a ground water source, to take disinfectant residual samples at points other than the total coliform sampling points if the State determines that such points are more representative of treated (disinfected) water quality within the distribution system.

Heterotrophic bacteria, measured as heterotrophic plate count (HPC) as specified in paragraph

(a)(1) of this section, may be measured in lieu of residual disinfectant concentration.

(c) ***

(3)(i) Until March 31, 2016, the residual disinfectant concentration must be measured at least at the same points in the distribution system and at the same time as total coliforms are sampled, as specified in § 141.21. Beginning April 1, 2016, the residual disinfectant concentration must be

measured at least at the same points in the distribution system and at the same time as total coliforms are sampled, as specified in §§ 141.854 through 141.858. The State may allow a public water system which uses both a surface water source or a ground water source under direct influence of surface water, and a ground water source, to take disinfectant residual samples at points other than the total coliform sampling points if the State determines that such points are more representative of treated (disinfected) water quality within the distribution system.

Heterotrophic bacteria, measured as heterotrophic plate count (HPC) as specified in paragraph (a)(1) of this section, may be measured in lieu of residual disinfectant concentration.

9. Section 141.132 is amended by revising paragraph (c)(1)(i) to read as follows:

§ 141.132 Monitoring requirements.

(c) ***

(1) ***

(i) *Routine monitoring.* Until March 31, 2016, community and non-transient non-community water systems that use chlorine or chloramines must measure the residual disinfectant level in the distribution system at the same point in the distribution system and at the same time as total coliforms are sampled, as specified in § 141.21. Beginning April 1, 2016, community and non-transient non-community water systems that use chlorine or chloramines must measure the residual disinfectant level in the distribution system at the same point in the distribution system and at the same time as total coliforms are sampled, as specified in §§ 141.854 through 141.858. Subpart H systems of this part may use the results of residual disinfectant concentration sampling

conducted under § 141.74(b)(6)(i) for unfiltered systems or § 141.74(c)(3)(i) for systems which filter, in lieu of taking separate samples.

10. Section 141.153 is amended as follows:

- a. By adding paragraphs (c)(4),
- b. By revising paragraph (d)(4)(iv) introductory text,
- c. By revising paragraph (d)(4)(vii) introductory text,
- d. By revising paragraph (d)(4)(viii),
- e. By adding paragraph (d)(4)(x), and
- f. By adding paragraph (h)(7).

§ 141.153 Content of the reports.

(c)***

(4) A report that contains information regarding a Level 1 or Level 2 Assessment required under Subpart Y of this part must include the applicable definitions: (i) *Level 1 Assessment*: A Level 1 assessment is a study of the water system to identify potential problems and determine (if possible) why total coliform bacteria have been found in our water system.

(ii) *Level 2 Assessment*: A Level 2 assessment is a very detailed study of the water system to identify potential problems and determine (if possible) why an *E. coli* MCL violation has occurred and/or why total coliform bacteria have been found in our water system on multiple occasions.

(d) ***

(4) ***

(iv) For contaminants subject to an MCL, except turbidity, total coliform, fecal coliform and *E. coli*, the highest contaminant level used to determine compliance with an NPDWR and the range of detected levels, as follows:

(vii) For total coliform analytical results until March 31, 2016:

(viii) For fecal coliform and *E. coli* until March 31, 2016: The total number of positive samples;

(x) For *E. coli* analytical results under subpart Y: The total number of positive samples.

(h)***

(7) *Systems required to comply with subpart Y.* (i) Any system required to comply with the Level 1 assessment requirement or a Level 2 assessment requirement that is not due to an *E. coli* MCL violation must include in the report the text found in paragraph (h)(7)(i)(A) and paragraphs (h)(7)(i)(B) and (C) of this section as appropriate, filling in the blanks accordingly and the text found in paragraphs (h)(7)(i)(D)(1) and (2) of this section if appropriate.

(A) Coliforms are bacteria that are naturally present in the environment and are used as an indicator that other, potentially harmful, waterborne pathogens may be present or that a potential pathway exists through which contamination may enter the drinking water distribution system.

We found coliforms indicating the need to look for potential problems in water treatment or distribution. When this occurs, we are required to conduct assessment(s) to identify problems and to correct any problems that were found during these assessments.

(B) During the past year we were required to conduct [INSERT NUMBER OF LEVEL 1 ASSESSMENTS] Level 1 assessment(s). [INSERT NUMBER OF LEVEL 1 ASSESSMENTS] Level 1 assessment(s) were completed. In addition, we were required to take [INSERT NUMBER OF CORRECTIVE ACTIONS] corrective actions and we completed [INSERT NUMBER OF CORRECTIVE ACTIONS] of these actions.

(C) During the past year [INSERT NUMBER OF LEVEL 2 ASSESSMENTS] Level 2 assessments were required to be completed for our water system. [INSERT NUMBER OF LEVEL 2 ASSESSMENTS] Level 2 assessments were completed. In addition, we were required to take [INSERT NUMBER OF CORRECTIVE ACTIONS] corrective actions and we completed [INSERT NUMBER OF CORRECTIVE ACTIONS] of these actions.

(D) Any system that has failed to complete all the required assessments or correct all identified sanitary defects, is in violation of the treatment technique requirement and must also include one or both of the following statements, as appropriate:

(1) During the past year we failed to conduct all of the required assessment(s).

(2) During the past year we failed to correct all identified defects that were found during the assessment.

(ii) Any system required to conduct a Level 2 assessment due to an *E. coli* MCL violation must include in the report the text found in paragraphs (h)(7)(ii)(A) and (B) of this section, filling in the blanks accordingly and the text found in paragraphs (h)(7)(ii)(C)(1) and (2) of this section, if appropriate.

(A) *E. coli* are bacteria whose presence indicates that the water may be contaminated with human or animal wastes. Human pathogens in these wastes can cause short-term effects, such as diarrhea, cramps, nausea, headaches, or other symptoms. They may pose a greater health risk for

infants, young children, the elderly, and people with severely compromised immune systems.

We found *E. coli* bacteria, indicating the need to look for potential problems in water treatment or distribution. When this occurs, we are required to conduct assessment(s) to identify problems and to correct any problems that were found during these assessments.

(B) We were required to complete a Level 2 assessment because we found *E. coli* in our water system. In addition, we were required to take [INSERT NUMBER OF CORRECTIVE ACTIONS] corrective actions and we completed [INSERT NUMBER OF CORRECTIVE ACTIONS] of these actions.

(C) Any system that has failed to complete the required assessment or correct all identified sanitary defects, is in violation of the treatment technique requirement and must also include one or both of the following statements, as appropriate:

(1) We failed to conduct the required assessment.

(2) We failed to correct all sanitary defects that were identified during the assessment that we conducted.

(iii) If a system detects *E. coli* and has violated the *E. coli* MCL, in addition to completing the table as required in paragraph (d)(4) of this section, the system must include one or more of the following statements to describe any noncompliance, as applicable:

(A) We had an *E. coli*-positive repeat sample following a total coliform-positive routine sample.

(B) We had a total coliform-positive repeat sample following an *E. coli*-positive routine sample.

(C) We failed to take all required repeat samples following an *E. coli*-positive routine sample.

(D) We failed to test for *E. coli* when any repeat sample tests positive for total coliform.

(iv) If a system detects *E. coli* and has not violated the *E. coli* MCL, in addition to completing the table as required in paragraph (d)(4) of this section, the system may include a statement that explains that although they have detected *E. coli*, they are not in violation of the *E. coli* MCL.

11. Appendix A to Subpart O of Part 141 is amended as follows:

- a. By revising the entries for “Total Coliform Bacteria” and “Fecal Coliform and *E. coli*,”
- b. By adding a second entry for “Total Coliform Bacteria,”
- c. By adding as a fourth entry “*E. coli*,” and
- d. By adding two endnotes before Endnote 1.

APPENDIX A TO SUBPART O OF PART 141 – REGULATED CONTAMINANTS

Contaminant (units)	Traditional MCL in mg/L	To convert for CCR, multiply by	MCL in CCR units	MCLG	Major sources in drinking water	Health effects language
Microbiological contaminants:						

Total Coliform Bacteria †	MCL (systems that collect ≥ 40 samples/month) 5% of monthly samples are positive; (systems that collect < 40 samples/month) 1 positive monthly sample	MCL (systems that collect ≥ 40 samples/month) 5% of monthly samples are positive; (systems that collect < 40 samples/month) 1 positive monthly sample.	0	Naturally present in the environment	Coliforms are bacteria that are naturally present in the environment and are used as an indicator that other, potentially-harmful, bacteria may be present. Coliforms were found in more samples than allowed and this was a warning of potential problems.
Total Coliform Bacteria ‡	TT		TT	N/A	Naturally present in the environment	Use language found in §141.153(h)(7)(i)(A)

Fecal coliform and <i>E. coli</i> †	0	0	0	Human and animal fecal waste	Fecal coliforms and <i>E. coli</i> are bacteria whose presence indicates that the water may be contaminated with human or animal wastes. Microbes in these wastes can cause short-term effects, such as diarrhea, cramps, nausea, headaches, or other symptoms. They may pose a special health risk for infants, young children, some of the elderly, and people with severely compromised immune systems.
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<i>E. coli</i> †	Routine and repeat samples are total coliform-positive and either is <i>E. coli</i> -positive or system fails to take repeat samples following <i>E. coli</i> -positive routine sample or system fails to analyze total coliform-positive repeat sample for <i>E. coli</i>	Routine and repeat samples are total coliform-positive and either is <i>E. coli</i> -positive or system fails to take repeat samples following <i>E. coli</i> -positive routine sample or system fails to analyze total coliform-positive repeat sample for <i>E. coli</i>	0	Human and animal fecal waste	<i>E. coli</i> are bacteria whose presence indicates that the water may be contaminated with human or animal wastes. Human pathogens in these wastes can cause short-term effects, such as diarrhea, cramps, nausea, headaches, or other symptoms. They may pose a greater health risk for infants, young children, the elderly, and people with severely-compromised immune systems.
*	*	*	*		*	*

† Until March 31, 2016.

‡ Beginning April 1, 2016.

12. Section 141.202(a), Table 1, is amended by adding one sentence at the end of entry one (1) to read as follows:

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

Table 1 to § 141.202 – Violation Categories and Other Situations Requiring A Tier 1 Public Notice

(1) *** Violation of the MCL for <i>E. coli</i> (as specified in §141.63(c));
* * * * *

13. Section 141.203(b)(2) is revised to read as follows:

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

(b) ***

(2) The public water system must repeat the notice every three months as long as the violation or situation persists, unless the primacy agency determines that appropriate circumstances warrant a different repeat notice frequency. In no circumstance may the repeat notice be given less frequently than once per year. It is not appropriate for the primacy agency to allow less frequent repeat notice for an MCL or treatment technique violation under the Total Coliform Rule or subpart Y of this part or a treatment technique violation under the Surface Water Treatment Rule or Interim Enhanced Surface Water Treatment Rule. It is also not appropriate for the primacy agency to allow through its rules or policies across-the-board reductions in the repeat notice frequency for other ongoing violations requiring a Tier 2 repeat notice. Primacy agency

determinations allowing repeat notices to be given less frequently than once every three months must be in writing.

14. Section 141.204(a), Table 1, is amended by revising entries (4) and (5) and adding entry (6) to read as follows:

§ 141.204 Tier 3 Public Notice – Form, manner, frequency of notice.

(a) ***

Table 1 to § 141.204 – Violation Categories and Other Situations Requiring a Tier 3 Public Notice

* * * * * * *
(4) Availability of unregulated contaminant monitoring results, as required under § 141.207;
(5) Exceedance of the fluoride secondary maximum contaminant level (SMCL), as required under § 141.208; and
(6) Reporting and Recordkeeping violations under subpart Y of 40 CFR part 141.

15. Appendix A to subpart Q of Part 141 is amended as follows:

- a. By revising entries I.A.1 and I.A.2,
- b. By adding two endnotes before Endnote 1, and
- c. By modifying Endnote 1.

APPENDIX A TO SUBPART Q OF PART 141 – NPDWR VIOLATIONS AND OTHER SITUATIONS REQUIRING PUBLIC NOTICE¹

Contaminant	MCL/MRDL/TT violations ²		Monitoring, testing & reporting procedure violations	
	Tier of public notice required	Citation	Tier of public notice required	Citation
I. Violations of National Primary Drinking Water Regulations (NPDWR): ³				
A. Microbiological Contaminants				
1.a Total coliform bacteria †	2	141.63(a)	3	141.21(a)-(e)
1.b Total coliform (Monitoring or TT violations resulting from failure to perform assessments or corrective actions) ‡	2	141.860(b)	3	141.860(c)
1.c Seasonal system failure to follow State-approved start-up plan prior to serving water to the public. ‡	2	141.860(b)(2)		
2.a Fecal coliform/ <i>E. coli</i> †	1	141.63(b)	⁴ 1,3	141.21(e)
2.b <i>E. coli</i> ‡	1	141.860 (a)	3	141.860(c) 141.860(d)(2)
2.c <i>E.coli</i> (TT violations resulting from failure to perform level 2 Assessments or corrective action) ‡	2	141.860(b)		
* * * * *	*	*	*	*

Appendix A—Endnotes

† Until March 31, 2016.

‡ Beginning April 1, 2016.

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

3. The term Violations of National Primary Drinking Water Regulations (NPDWR) is used here to include violations of MCL, MRDL, treatment technique, monitoring, and testing procedure requirements.
3. The term Violations of National Primary Drinking Water Regulations (NPDWR) is used here to include violations of MCL, MRDL, treatment technique, monitoring, and testing procedure requirements.
4. Failure to test for fecal coliform or E. coli is a Tier 1 violation if testing is not done after any repeat sample tests positive for coliform. All other total coliform monitoring and testing procedure violations are Tier 3.

16. Appendix B to subpart Q of Part 141 is amended as follows:

- a. By revising entries 1a and 1b,
- b. By adding entries 1e, 1f, 1g and 1h, and
- c. By adding two endnotes before Endnote 1.

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

Contaminant	MCLG¹mg/L	MCL²mg/L	Standard health effects language for public notification
National Primary Drinking Water Regulations (NPDWR)			
A. Microbiological Contaminants			
1a. Total coliform †	Zero	See footnote ³	Coliforms are bacteria that are naturally present in the environment and are used as an indicator that other, potentially-harmful, bacteria may be present. Coliforms were found in more samples than allowed and this was a warning of potential problems.

1b. Fecal coliform/ <i>E. coli</i> †	Zero	Zero	Fecal coliforms and <i>E. coli</i> are bacteria whose presence indicates that the water may be contaminated with human or animal wastes. Microbes in these wastes can cause short-term effects, such as diarrhea, cramps, nausea, headaches, or other symptoms. They may pose a special health risk for infants, young children, some of the elderly, and people with severely compromised immune systems.
* * * * *			
1e. Subpart Y Coliform Assessment and/or Corrective Action Violations ‡	N/A	TT ³	<p>Coliforms are bacteria that are naturally present in the environment and are used as an indicator that other, potentially harmful, waterborne pathogens may be present or that a potential pathway exists through which contamination may enter the drinking water distribution system. We found coliforms indicating the need to look for potential problems in water treatment or distribution. When this occurs, we are required to conduct assessments to identify problems and to correct any problems that are found.</p> <p>[THE SYSTEM MUST USE THE FOLLOWING APPLICABLE SENTENCES.]</p> <p>We failed to conduct the required assessment.</p> <p>We failed to correct all identified sanitary defects that were found during the assessment(s).</p>

<p>1f. Subpart Y <i>E.coli</i> Assessment and/or Corrective Action Violations ‡</p>	<p>N/A</p>	<p>TT³</p>	<p><i>E. coli</i> are bacteria whose presence indicates that the water may be contaminated with human or animal wastes. Human pathogens in these wastes can cause short-term effects, such as diarrhea, cramps, nausea, headaches, or other symptoms. They may pose a greater health risk for infants, young children, the elderly, and people with severely compromised immune systems. We violated the standard for <i>E. coli</i>, indicating the need to look for potential problems in water treatment or distribution. When this occurs, we are required to conduct a detailed assessment to identify problems and to correct any problems that are found. [THE SYSTEM MUST USE THE FOLLOWING APPLICABLE SENTENCES.] We failed to conduct the required assessment. We failed to correct all identified sanitary defects that were found during the assessment that we conducted.</p>
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1g. <i>E. coli</i> ‡	Zero	In compliance unless one of the following conditions occurs: (1) The system has an <i>E. coli</i> -positive repeat sample following a total coliform-positive routine sample. (2) The system has a total coliform-positive repeat sample following an <i>E. coli</i> -positive routine sample. (3) The system fails to take all required repeat samples following an <i>E. coli</i> -positive routine sample. (4) The system fails to test for <i>E. coli</i> when any repeat sample tests positive for total coliform.	<i>E. coli</i> are bacteria whose presence indicates that the water may be contaminated with human or animal wastes. Human pathogens in these wastes can cause short-term effects, such as diarrhea, cramps, nausea, headaches, or other symptoms. They may pose a greater health risk for infants, young children, the elderly, and people with severely compromised immune systems.
1h. Subpart Y Seasonal System TT Violations ‡	N/A	TT ³	When this violation includes the failure to monitor for total coliforms or <i>E. coli</i> prior to serving water to the public, the mandatory language found at 141.205(d)(2) must be used. When this violation includes failure to complete other actions, the appropriate elements found in 141.205(a) to describe the violation must be used.
*	*	*	*

Appendix B—Endnotes

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

3. For water systems analyzing at least 40 samples per month, no more than 5.0 percent of the monthly samples may be positive for total coliforms. For systems analyzing fewer than 40 samples per month, no more than one sample per month may be positive for total coliforms.

† Until March 31, 2016.

‡ Beginning April 1, 2016.

17. Section 141.402 is amended by revising paragraph (a) to read as follows:

§ 141.402 Ground water source microbial monitoring and analytical methods.

(a) *Triggered source water monitoring*—

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

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

(ii) The system is notified that a sample collected under § 141.21(a) is total coliform-positive and the sample is not invalidated under § 141.21(c) until March 31, 2016, or

(iii) The system is notified that a sample collected under §§ 141.854 through 141.857 is total coliform-positive and the sample is not invalidated under § 141.853(c) beginning April 1, 2016.

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

until March 31, 2016, or collected under §§ 141.854 through 141.857 beginning April 1, 2016, except as provided in paragraph (a)(2)(ii) of this section.

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

(ii) If approved by the State, systems with more than one ground water source may meet the requirements of this paragraph (a)(2) by sampling a representative ground water source or sources. If directed by the State, systems must submit for State approval a triggered source water monitoring plan that identifies one or more ground water sources that are representative of each monitoring site in the system's sample siting plan under § 141.21(a) until March 31, 2016, or under § 141.853 beginning April 1, 2016, and that the system intends to use for representative sampling under this paragraph.

(iii) Until March 31, 2016, a ground water system serving 1,000 or fewer people may use a repeat sample collected from a ground water source to meet both the requirements of § 141.21(b) and to satisfy the monitoring requirements of paragraph (a)(2) of this section for that ground water source only if the State approves the use of *E. coli* as a fecal indicator for source water monitoring under this paragraph (a). If the repeat sample collected from the ground water source is *E. coli*-positive, the system must comply with paragraph (a)(3) of this section.

(iv) Beginning April 1, 2016, a ground water system serving 1,000 or fewer people may use a repeat sample collected from a ground water source to meet both the requirements of subpart Y and to satisfy the monitoring requirements of paragraph (a)(2) of this section for that ground water source only if the State approves the use of *E. coli* as a fecal indicator for source water

monitoring under this paragraph (a) and approves the use of a single sample for meeting both the triggered source water monitoring requirements in this paragraph (a) and the repeat monitoring requirements in § 141.858. If the repeat sample collected from the ground water source is *E. coli*-positive, the system must comply with paragraph (a)(3) of this section.

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

(4) *Consecutive and wholesale systems—*

(i) In addition to the other requirements of this paragraph (a), a consecutive ground water system that has a total coliform-positive sample collected under § 141.21(a) until March 31, 2016, or under §§ 141.854 through 141.857 beginning April 1, 2016, must notify the wholesale system(s) within 24 hours of being notified of the total coliform-positive sample.

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

(A) A wholesale ground water system that receives notice from a consecutive system it serves that a sample collected under § 141.21(a) until March 31, 2016, or collected under §§ 141.854 through 141.857 beginning April 1, 2016, is total coliform-positive must, within 24 hours of being notified, collect a sample from its ground water source(s) under paragraph(a)(2) of this section and analyze it for a fecal indicator under paragraph (c) of this section.

(B) If the sample collected under paragraph (a)(4)(ii)(A) of this section is fecal indicator-positive, the wholesale ground water system must notify all consecutive systems served by that

ground water source of the fecal indicator source water positive within 24 hours of being notified of the ground water source sample monitoring result and must meet the requirements of paragraph (a)(3) of this section.

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

(i) The State determines, and documents in writing, that the total coliform-positive sample collected under § 141.21(a) until March 31, 2016, or under §§ 141.854 through 141.857 beginning April 1, 2016, is caused by a distribution system deficiency; or

(ii) The total coliform-positive sample collected under § 141.21(a) until March 31, 2016, or under §§ 141.854 through 141.857 beginning April 1, 2016, is collected at a location that meets State criteria for distribution system conditions that will cause total coliform-positive samples.

18. Section 141.405 is amended by revising paragraph (b)(4) to read as follows:

§ 141.405 Reporting and recordkeeping for ground water systems.

(b) ***

(4) For consecutive systems, documentation of notification to the wholesale system(s) of total coliform-positive samples that are not invalidated under § 141.21(c) until March 31, 2016, or under § 141.853 beginning April 1, 2016. Documentation shall be kept for a period of not less than five years.

19. Section 141.803 is amended by revising paragraphs (a)(3) and (a)(5) to read as follows:

§ 141.803 Coliform sampling.

(a) ***

(3) Air carriers must conduct analyses for total coliform and *E. coli* in accordance with the analytical methods approved in §§ 141.21(f)(3) and 141.21(f)(6)) until March 31, 2016, and in accordance with the analytical methods approved in § 141.852 beginning April 1, 2016.

(5) The invalidation of a total coliform sample result can be made only by the Administrator in accordance with §§ 141.21(c)(1)(i), (ii), or (iii) or by the certified laboratory in accordance with § 141.21(c)(2) until March 31, 2016, or in accordance with § 141.853(c) beginning April 1, 2016, with the Administrator acting as the State.

20. Part 141 is amended by adding a new subpart Y to read as follows:

Subpart Y - Revised Total Coliform Rule

Sec.

141.851 General.

141.852 Analytical methods and laboratory certification.

141.853 General monitoring requirements for all public water systems.

141.854 Routine monitoring requirements for non-community water systems serving 1,000 or fewer people using only ground water.

141.855 Routine monitoring requirements for community water systems serving 1,000 or fewer people using only ground water.

141.856 Routine monitoring requirements for subpart H public water systems of this part serving 1,000 or fewer people.

141.857 Routine monitoring requirements for public water systems serving more than 1,000 people.

141.858 Repeat monitoring and *E. coli* requirements.

141.859 Coliform treatment technique triggers and assessment requirements for protection against potential fecal contamination.

141.860 Violations.

141.861 Reporting and recordkeeping.

Subpart Y - Revised Total Coliform Rule

§ 141.851 General.

(a) *General.* The provisions of this subpart include both maximum contaminant level and treatment technique requirements.

(b) *Applicability.* The provisions of this subpart apply to all public water systems.

(c) *Compliance date.* Systems must comply with the provisions of this subpart beginning April 1, 2016, unless otherwise specified in this subpart.

(d) *Implementation with EPA as State.* Systems falling under direct oversight of EPA, where EPA acts as the State, must comply with decisions made by EPA for implementation of subpart Y. EPA has authority to establish such procedures and criteria as are necessary to implement subpart Y.

(e) *Violations of national primary drinking water regulations.* Failure to comply with the applicable requirements of §§ 141.851 through 141.861, including requirements established by the State pursuant to these provisions, is a violation of the national primary drinking water regulations under subpart Y.

§ 141.852 Analytical methods and laboratory certification.

(a) *Analytical methodology.* (1) The standard sample volume required for analysis, regardless of analytical method used, is 100 ml.

(2) Systems need only determine the presence or absence of total coliforms and *E. coli*; a determination of density is not required.

(3) The time from sample collection to initiation of test medium incubation may not exceed 30 hours. Systems are encouraged but not required to hold samples below 10 deg. C during transit.

(4) If water having residual chlorine (measured as free, combined, or total chlorine) is to be analyzed, sufficient sodium thiosulfate (Na₂S₂O₃) must be added to the sample bottle before sterilization to neutralize any residual chlorine in the water sample. Dechlorination procedures are addressed in Section 9060A.2 of *Standard Methods for the Examination of Water and Wastewater* (20th and 21st editions).

(5) Systems must conduct total coliform and *E. coli* analyses in accordance with one of the analytical methods in the following table or one of the alternative methods listed in Appendix A to subpart C of part 141.

Organism	Methodology Category	Method ¹	Citation ¹
Total Coliforms			

	Lactose Fermentation Methods	Standard Total Coliform Fermentation Technique	Standard Methods 9221 B.1, B.2 (20 th ed.; 21 st ed.) ^{2,3} Standard Methods Online 9221 B.1, B.2-99 ^{2,3}
		Presence-Absence (P-A) Coliform Test	Standard Methods 9221 D.1, D.2 (20 th ed.; 21 st ed.) ^{2,7} Standard Methods Online 9221 D.1, D.2-99 ^{2,7}
	Membrane Filtration Methods	Standard Total Coliform Membrane Filter Procedure	Standard Methods 9222 B, C (20 th ed.; 21 st ed.) ^{2,4} Standard Methods Online 9222 B-97 ^{2,4} , 9222 C-97 ^{2,4}
		Membrane Filtration using MI medium	EPA Method 1604 ²
		m-ColiBlue24® Test ^{2,4} Chromocult ^{2,4}	
	Enzyme Substrate Methods	Colilert®	Standard Methods 9223 B (20 th ed.; 21 st ed.) ^{2,5} Standard Methods Online 9223 B-97 ^{2,5}
		Colisure®	Standard Methods 9223 B (20 th ed.; 21 st ed.) ^{2,5,6} Standard Methods Online 9223 B-97 ^{2,5,6}
		E*Colite® Test ²	
Readycult® Test ²			
modified Colitag® Test ²			
<i>Escherichia coli</i>			

	<i>Escherichia coli</i> Procedure (following Lactose Fermentation Methods)	EC-MUG medium	Standard Methods 9221 F.1 (20 th ed.; 21 st ed.) ²
	<i>Escherichia coli</i> Partition Method	EC broth with MUG (EC- MUG)	Standard Methods 9222 G.1c(2) (20 th ed.; 21 st ed.) ^{2, 8}
		NA-MUG medium	Standard Methods 9222 G.1c(1) (20 th ed.; 21 st ed.) ²
	Membrane Filtration Methods	Membrane Filtration using MI medium	EPA Method 1604 ²
		m-ColiBlue24® Test ^{2, 4}	
		Chromocult ^{2, 4}	
	Enzyme Substrate Methods	Colilert®	Standard Methods 9223 B (20 th ed.; 21 st ed.) ^{2, 5} Standard Methods Online 9223 B-97 ^{2, 5, 6}
Colisure®		Standard Methods 9223 B (20 th ed.; 21 st ed.) ^{2, 5, 6} Standard Methods Online 9223 B-97 ^{2, 5, 6}	
E*Colite® Test ²			
Readycult® Test ²			
modified Colitag® Test ²			

¹ The procedures must be done in accordance with the documents listed in paragraph (c) of this section. For Standard Methods, either editions, 20th (1998) or 21st (2005), may be used. For the Standard Methods Online, the year in which each method was approved by the Standard Methods Committee is designated by the last two digits following the hyphen in the method number. The methods listed are the only online versions that may be used. For vendor methods, the date of the method listed in paragraph (c) of this section is the date/version of the approved method. The methods listed are the only versions that may be used for compliance with this rule. Laboratories should be careful to use only the approved versions of the methods, as product package inserts may not be the same as the approved versions of the methods.

² Incorporated by reference. See paragraph (c) of this section.

³ Lactose broth, as commercially available, may be used in lieu of lauryl tryptose broth, if the system conducts at least 25 parallel tests between lactose broth and lauryl tryptose broth using the water

normally tested, and if the findings from this comparison demonstrate that the false-positive rate and false-negative rate for total coliforms, using lactose broth, is less than 10 percent.

⁴ All filtration series must begin with membrane filtration equipment that has been sterilized by autoclaving. Exposure of filtration equipment to UV light is not adequate to ensure sterilization. Subsequent to the initial autoclaving, exposure of the filtration equipment to UV light may be used to sanitize the funnels between filtrations within a filtration series. Alternatively, membrane filtration equipment that is pre-sterilized by the manufacturer (i.e., disposable funnel units) may be used.

⁵ Multiple-tube and multi-well enumerative formats for this method are approved for use in presence-absence determination under this regulation.

⁶ Colisure® results may be read after an incubation time of 24 hours.

⁷ A multiple tube enumerative format, as described in *Standard Methods for the Examination of Water and Wastewater* 9221, is approved for this method for use in presence-absence determination under this regulation.

⁸ The following changes must be made to the EC broth with MUG (EC-MUG) formulation: Potassium dihydrogen phosphate, KH_2PO_4 , must be 1.5g, and 4-methylumbelliferyl-Beta-D-glucuronide must be 0.05 g.

(b) *Laboratory certification.* Systems must have all compliance samples required under this subpart analyzed by a laboratory certified by the EPA or a primacy State to analyze drinking water samples. The laboratory used by the system must be certified for each method (and associated contaminant(s)) used for compliance monitoring analyses under this rule.

(c) *Incorporation by reference.* The standards required in this section are incorporated by reference into this section with the approval of the Director of the Federal Register under 5 U.S.C. 552(a) and 1 CFR part 51. To enforce any edition other than that specified in this section, EPA must publish notice of change in the *Federal Register* and the material must be available to the public. All approved material is available for inspection either electronically at www.regulations.gov, in hard copy at the Water Docket, or from the sources indicated below. The Docket ID is EPA-HQ-OW-2008-0878. Hard copies of these documents may be viewed at the Water Docket in the EPA Docket Center, (EPA/DC) EPA West, Room 3334, 1301 Constitution Ave., NW, Washington, DC. The EPA Docket Center Public Reading Room is

open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is 1-202-566-1744, and the telephone number for the Water Docket is 1-202-566-2426. Copyrighted materials are only available for viewing in hard copy. These documents are also available for inspection at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 1-202-741-6030 or go to:

http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.

(1) American Public Health Association, 800 I Street, NW, Washington, DC 20001

(i) “Standard Methods for the Examination of Water and Wastewater,” 20th edition (1998):

(A) Standard Methods 9221, “Multiple-Tube Fermentation Technique for Members of the Coliform Group,” B.1, B.2, “Standard Total Coliform Fermentation Technique.”

(B) Standard Methods 9221, “Multiple-Tube Fermentation Technique for Members of the Coliform Group,” D.1, D.2, “Presence-Absence (P-A) Coliform Test.”

(C) Standard Methods 9222, “Membrane Filter Technique for Members of the Coliform Group,” B, “Standard Total Coliform Membrane Filter Procedure.”

(D) Standard Methods 9222, “Membrane Filter Technique for Members of the Coliform Group,” C, “Delayed-Incubation Total Coliform Procedure.”

(E) Standard Methods 9223, “Enzyme Substrate Coliform Test,” B, “Enzyme Substrate Test,” Colilert® and Colisure®.

(F) Standard Methods 9221, “Multiple Tube Fermentation Technique for Members of the Coliform Group,” F.1, “*Escherichia coli* Procedure: EC-MUG medium.”

(G) Standard Methods 9222, “Membrane Filter Technique for Members of the Coliform Group,” G.1.c(2), “*Escherichia coli* Partition Method: EC broth with MUG (EC-MUG).”

- (H) Standard Methods 9222, “Membrane Filter Technique for Members of the Coliform Group,” G.1.c(1), “*Escherichia coli* Partition Method: NA-MUG medium.”
- (ii) “Standard Methods for the Examination of Water and Wastewater,” 21st edition (2005):
- (A) Standard Methods 9221, “Multiple-Tube Fermentation Technique for Members of the Coliform Group,” B.1, B.2, “Standard Total Coliform Fermentation Technique.”
- (B) Standard Methods 9221, “Multiple-Tube Fermentation Technique for Members of the Coliform Group,” D.1, D.2, “Presence-Absence (P-A) Coliform Test.”
- (C) Standard Methods 9222, “Membrane Filter Technique for Members of the Coliform Group,” B, “Standard Total Coliform Membrane Filter Procedure.”
- (D) Standard Methods 9222, “Membrane Filter Technique for Members of the Coliform Group,” C, “Delayed-Incubation Total Coliform Procedure.”
- (E) Standard Methods 9223, “Enzyme Substrate Coliform Test,” B, “Enzyme Substrate Test,” Colilert® and Colisure®.
- (F) Standard Methods 9221, “Multiple Tube Fermentation Technique for Members of the Coliform Group,” F.1, “*Escherichia coli* Procedure: EC-MUG medium.”
- (G) Standard Methods 9222, “Membrane Filter Technique for Members of the Coliform Group,” G.1.c(2), “*Escherichia coli* Partition Method: EC broth with MUG (EC-MUG).”
- (H) Standard Methods 9222, “Membrane Filter Technique for Members of the Coliform Group,” G.1.c(1), “*Escherichia coli* Partition Method: NA-MUG medium.”
- (iii) “Standard Methods Online” available at <http://www.standardmethods.org>:
- (A) Standard Methods Online 9221, “Multiple-Tube Fermentation Technique for Members of the Coliform Group” (1999), B.1, B.2-99, “Standard Total Coliform Fermentation Technique.”

(B) Standard Methods Online 9221, “Multiple-Tube Fermentation Technique for Members of the Coliform Group” (1999), D.1, D.2-99, “Presence-Absence (P-A) Coliform Test.”

(C) Standard Methods Online 9222, “Membrane Filter Technique for Members of the Coliform Group” (1997), B-97, “Standard Total Coliform Membrane Filter Procedure.”

(D) Standard Methods Online 9222, “Membrane Filter Technique for Members of the Coliform Group” (1997), C-97, “Delayed-Incubation Total Coliform Procedure.”

(E) Standard Methods Online 9223, “Enzyme Substrate Coliform Test” (1997), B-97, “Enzyme Substrate Test”, Colilert® and Colisure®.

(2) Charm Sciences, Inc., 659 Andover Street, Lawrence, MA 01843-1032, telephone 1-800-343-2170:

(i) E*Colite® – “Charm E*Colite™ Presence/Absence Test for Detection and Identification of Coliform Bacteria and *Escherichia coli* in Drinking Water,” January 9, 1998.

(ii) [Reserved]

(3) CPI International, Inc., 5580 Skylane Blvd., Santa Rosa, CA, 95403, telephone 1-800-878-7654:

(i) modified Colitag®, ATP D05-0035 – “Modified Colitag™ Test Method for the Simultaneous Detection of *E. coli* and other Total Coliforms in Water,” August 28, 2009.

(ii) [Reserved]

(4) EMD Millipore (a division of Merck KGaA, Darmstadt Germany), 290 Concord Road, Billerica, MA 01821, telephone 1-800-645-5476:

(i) Chromocult – “Chromocult® Coliform Agar Presence/Absence Membrane Filter Test Method for Detection and Identification of Coliform Bacteria and *Escherichia coli* for Finished Waters,” November 2000, Version 1.0.

(ii) ReadyCult® – “ReadyCult® Coliforms 100 Presence/Absence Test for Detection and Identification of Coliform Bacteria and *Escherichia coli* in Finished Waters,” January 2007, Version 1.1.

(5) EPA’s Water Resource Center (MC-4100T), 1200 Pennsylvania Avenue, NW, Washington, DC 20460, telephone 1-202-566-1729:

(i) EPA Method 1604, EPA 821-R-02-024 – “EPA Method 1604: Total Coliforms and *Escherichia coli* in Water by Membrane Filtration Using a Simultaneous Detection Technique (MI Medium),” September 2002, <http://www.epa.gov/nerlcwww/1604sp02.pdf>.

(ii) [Reserved]

(6) Hach Company, P.O. Box 389, Loveland, CO 80539, telephone 1-800-604-3493:

(i) m-ColiBlue24® – “Membrane Filtration Method m-ColiBlue24® Broth,” Revision 2, August 17, 1999.

(ii) [Reserved]

§ 141.853 General monitoring requirements for all public water systems.

(a) *Sample siting plans.* (1) Systems must develop a written sample siting plan that identifies sampling sites and a sample collection schedule that are representative of water throughout the distribution system not later than March 31, 2016. These plans are subject to State review and revision. Systems must collect total coliform samples according to the written sample siting plan. Monitoring required by §§ 141.854 through 141.858 may take place at a customer’s premise, dedicated sampling station, or other designated compliance sampling location. Routine and repeat sample sites and any sampling points necessary to meet the requirements of subpart S must be reflected in the sampling plan.

(2) Systems must collect samples at regular time intervals throughout the month, except that

systems that use only ground water and serve 4,900 or fewer people may collect all required samples on a single day if they are taken from different sites.

(3) Systems must take at least the minimum number of required samples even if the system has had an *E. coli* MCL violation or has exceeded the coliform treatment technique triggers in § 141.859(a).

(4) A system may conduct more compliance monitoring than is required by this subpart to investigate potential problems in the distribution system and use monitoring as a tool to assist in uncovering problems. A system may take more than the minimum number of required routine samples and must include the results in calculating whether the coliform treatment technique trigger in §141.859(a)(1)(i) and (ii) has been exceeded only if the samples are taken in accordance with the existing sample siting plan and are representative of water throughout the distribution system.

(5) Systems must identify repeat monitoring locations in the sample siting plan. Unless the provisions of paragraphs (a)(5)(i) or (a)(5)(ii) of this section are met, the system must collect at least one repeat sample from the sampling tap where the original total coliform-positive sample was taken, and at least one repeat sample at a tap within five service connections upstream and at least one repeat sample at a tap within five service connections downstream of the original sampling site. If a total coliform-positive sample is at the end of the distribution system, or one service connection away from the end of the distribution system, the system must still take all required repeat samples. However, the State may allow an alternative sampling location in lieu of the requirement to collect at least one repeat sample upstream or downstream of the original sampling site. Except as provided for in paragraph (a)(5)(ii) of this section, systems required to

conduct triggered source water monitoring under § 141.402(a) must take ground water source sample(s) in addition to repeat samples required under this subpart.

(i) Systems may propose repeat monitoring locations to the State that the system believes to be representative of a pathway for contamination of the distribution system. A system may elect to specify either alternative fixed locations or criteria for selecting repeat sampling sites on a situational basis in a standard operating procedure (SOP) in its sample siting plan. The system must design its SOP to focus the repeat samples at locations that best verify and determine the extent of potential contamination of the distribution system area based on specific situations. The State may modify the SOP or require alternative monitoring locations as needed.

(ii) Ground water systems serving 1,000 or fewer people may propose repeat sampling locations to the State that differentiate potential source water and distribution system contamination (e.g., by sampling at entry points to the distribution system). A ground water system with a single well required to conduct triggered source water monitoring may, with written State approval, take one of its repeat samples at the monitoring location required for triggered source water monitoring under § 141.402(a) if the system demonstrates to the State's satisfaction that the sample siting plan remains representative of water quality in the distribution system. If approved by the State, the system may use that sample result to meet the monitoring requirements in both § 141.402(a) and this section.

(A) If a repeat sample taken at the monitoring location required for triggered source water monitoring is *E. coli*-positive, the system has violated the *E. coli* MCL and must also comply with § 141.402(a)(3). If a system takes more than one repeat sample at the monitoring location required for triggered source water monitoring, the system may reduce the number of additional

source water samples required under § 141.402(a)(3) by the number of repeat samples taken at that location that were not *E. coli*-positive.

(B) If a system takes more than one repeat sample at the monitoring location required for triggered source water monitoring under § 141.402(a), and more than one repeat sample is *E. coli*-positive, the system has violated the *E. coli* MCL and must also comply with § 141.403(a)(1).

(C) If all repeat samples taken at the monitoring location required for triggered source water monitoring are *E. coli*-negative and a repeat sample taken at a monitoring location other than the one required for triggered source water monitoring is *E. coli*-positive, the system has violated the *E. coli* MCL, but is not required to comply with § 141.402(a)(3).

(6) States may review, revise, and approve, as appropriate, repeat sampling proposed by systems under paragraphs (a)(5)(i) and (ii) of this section. The system must demonstrate that the sample siting plan remains representative of the water quality in the distribution system. The State may determine that monitoring at the entry point to the distribution system (especially for undisinfected ground water systems) is effective to differentiate between potential source water and distribution system problems.

(b) *Special purpose samples.* Special purpose samples, such as those taken to determine whether disinfection practices are sufficient following pipe placement, replacement, or repair, must not be used to determine whether the coliform treatment technique trigger has been exceeded. Repeat samples taken pursuant to § 141.858 are not considered special purpose samples, and must be used to determine whether the coliform treatment technique trigger has been exceeded.

(c) *Invalidation of total coliform samples.* A total coliform-positive sample invalidated under this paragraph (c) of this section does not count toward meeting the minimum monitoring requirements of this subpart.

(1) The State may invalidate a total coliform-positive sample only if the conditions of paragraph (c)(1)(i), (ii), or (iii) of this section are met.

(i) The laboratory establishes that improper sample analysis caused the total coliform-positive result.

(ii) The State, on the basis of the results of repeat samples collected as required under § 141.858(a), determines that the total coliform-positive sample resulted from a domestic or other non-distribution system plumbing problem. The State cannot invalidate a sample on the basis of repeat sample results unless all repeat sample(s) collected at the same tap as the original total coliform-positive sample are also total coliform-positive, and all repeat samples collected at a location other than the original tap are total coliform-negative (e.g., a State cannot invalidate a total coliform-positive sample on the basis of repeat samples if all the repeat samples are total coliform-negative, or if the system has only one service connection).

(iii) The State has substantial grounds to believe that a total coliform-positive result is due to a circumstance or condition that does not reflect water quality in the distribution system. In this case, the system must still collect all repeat samples required under § 141.858(a), and use them to determine whether a coliform treatment technique trigger in § 141.859 has been exceeded. To invalidate a total coliform-positive sample under this paragraph, the decision and supporting rationale must be documented in writing, and approved and signed by the supervisor of the State official who recommended the decision. The State must make this document available to EPA and the public. The written documentation must state the specific cause of the total coliform-

positive sample, and what action the system has taken, or will take, to correct this problem. The State may not invalidate a total coliform-positive sample solely on the grounds that all repeat samples are total coliform-negative.

(2) A laboratory must invalidate a total coliform sample (unless total coliforms are detected) if the sample produces a turbid culture in the absence of gas production using an analytical method where gas formation is examined (e.g., the Multiple-Tube Fermentation Technique), produces a turbid culture in the absence of an acid reaction in the Presence-Absence (P-A) Coliform Test, or exhibits confluent growth or produces colonies too numerous to count with an analytical method using a membrane filter (e.g., Membrane Filter Technique). If a laboratory invalidates a sample because of such interference, the system must collect another sample from the same location as the original sample within 24 hours of being notified of the interference problem, and have it analyzed for the presence of total coliforms. The system must continue to re-sample within 24 hours and have the samples analyzed until it obtains a valid result. The State may waive the 24-hour time limit on a case-by-case basis. Alternatively, the State may implement criteria for waiving the 24-hour sampling time limit to use in lieu of case-by-case extensions.

§ 141.854 Routine monitoring requirements for non-community water systems serving 1,000 or fewer people using only ground water.

(a) *General.* (1) The provisions of this section apply to non-community water systems using only ground water (except ground water under the direct influence of surface water, as defined in § 141.2) and serving 1,000 or fewer people.

(2) Following any total coliform-positive sample taken under the provisions of this section, systems must comply with the repeat monitoring requirements and *E. coli* analytical requirements in § 141.858.

(3) Once all monitoring required by this section and § 141.858 for a calendar month has been completed, systems must determine whether any coliform treatment technique triggers specified in § 141.859 have been exceeded. If any trigger has been exceeded, systems must complete assessments as required by § 141.859.

(4) For the purpose of determining eligibility for remaining on or qualifying for quarterly monitoring under the provisions of paragraphs (f)(4) and (g)(2), respectively, of this section for transient non-community water systems, the State may elect to not count monitoring violations under § 141.860(c)(1) of this part if the missed sample is collected no later than the end of the monitoring period following the monitoring period in which the sample was missed. The system must collect the make-up sample in a different week than the routine sample for that monitoring period and should collect the sample as soon as possible during the monitoring period. The State may not use this provision under paragraph (h) of this section. This authority does not affect the provisions of §§ 141.860(c)(1) and 141.861(a)(4) of this part.

(b) *Monitoring frequency for total coliforms.* Systems must monitor each calendar quarter that the system provides water to the public, except for seasonal systems or as provided under paragraphs (c) through (h) and (j) of this section. Seasonal systems must meet the monitoring requirements of paragraph (i) of this section.

(c) *Transition to subpart Y.* (1) Systems, including seasonal systems, must continue to monitor according to the total coliform monitoring schedules under § 141.21 that were in effect on March

31, 2016, unless any of the conditions for increased monitoring in paragraph (f) of this section are triggered on or after April 1, 2016, or unless otherwise directed by the State.

(2) Beginning April 1, 2016, the State must perform a special monitoring evaluation during each sanitary survey to review the status of the system, including the distribution system, to determine whether the system is on an appropriate monitoring schedule. After the State has performed the special monitoring evaluation during each sanitary survey, the State may modify the system's monitoring schedule, as necessary, or it may allow the system to stay on its existing monitoring schedule, consistent with the provisions of this section. The State may not allow systems to begin less frequent monitoring under the special monitoring evaluation unless the system has already met the applicable criteria for less frequent monitoring in this section. For seasonal systems on quarterly or annual monitoring, this evaluation must include review of the approved sample siting plan, which must designate the time period(s) for monitoring based on site-specific considerations (e.g., during periods of highest demand or highest vulnerability to contamination). The seasonal system must collect compliance samples during these time periods.

(d) *Annual site visits.* Beginning no later than calendar year 2017, systems on annual monitoring, including seasonal systems, must have an initial and recurring annual site visit by the State that is equivalent to a Level 2 assessment or an annual voluntary Level 2 assessment that meets the criteria in §141.859(b) to remain on annual monitoring. The periodic required sanitary survey may be used to meet the requirement for an annual site visit for the year in which the sanitary survey was completed.

(e) *Criteria for annual monitoring.* Beginning April 1, 2016, the State may reduce the monitoring frequency for a well-operated ground water system from quarterly routine monitoring to no less than annual monitoring, if the system demonstrates that it meets the

criteria for reduced monitoring in paragraphs (e)(1) through (e)(3) of this section, except for a system that has been on increased monitoring under the provisions of paragraph (f) of this section. A system on increased monitoring under paragraph (f) of this section must meet the provisions of paragraph (g) of this section to go to quarterly monitoring and must meet the provisions of paragraph (h) of this section to go to annual monitoring.

(1) The system has a clean compliance history for a minimum of 12 months;

(2) The most recent sanitary survey shows that the system is free of sanitary defects or has corrected all identified sanitary defects, has a protected water source, and meets approved construction standards; and

(3) The State has conducted an annual site visit within the last 12 months and the system has corrected all identified sanitary defects. The system may substitute a Level 2 assessment that meets the criteria in §141.859(b) for the State annual site visit.

(f) Increased Monitoring Requirements for systems on quarterly or annual monitoring. A system on quarterly or annual monitoring that experiences any of the events identified in paragraphs (f)(1) through (f)(4) of this section must begin monthly monitoring the month following the event. A system on annual monitoring that experiences the event identified in paragraphs (f)(5) of this section must begin quarterly monitoring the quarter following the event. The system must continue monthly or quarterly monitoring until the requirements in paragraph (g) of this section for quarterly monitoring or paragraph (h) of this section for annual monitoring are met. A system on monthly monitoring for reasons other than those identified in paragraphs (f)(1) through (f)(4) of this section is not considered to be on increased monitoring for the purposes of paragraphs (g) and (h) of this section.

- (1) The system triggers a Level 2 assessment or two Level 1 assessments under the provisions of §141.859 in a rolling 12-month period.
 - (2) The system has an *E. coli* MCL violation.
 - (3) The system has a coliform treatment technique violation.
 - (4) The system has two subpart Y monitoring violations or one subpart Y monitoring violation and one Level 1 assessment under the provisions of § 141.859 in a rolling 12-month period for a system on quarterly monitoring.
 - (5) The system has one subpart Y monitoring violation for a system on annual monitoring.
- (g) *Requirements for returning to quarterly monitoring.* The State may reduce the monitoring frequency for a system on monthly monitoring triggered under paragraph (f) of this section to quarterly monitoring if the system meets the criteria in paragraphs (g)(1) and (g)(2) of this section.
- (1) Within the last 12 months, the system must have a completed sanitary survey or a site visit by the State or a voluntary Level 2 assessment by a party approved by the State, be free of sanitary defects, and have a protected water source; and
 - (2) The system must have a clean compliance history for a minimum of 12 months.
- (h) *Requirements for systems on increased monitoring to qualify for annual monitoring.* The State may reduce the monitoring frequency for a system on increased monitoring under paragraph (f) of this section if the system meets the criteria in paragraph (g) of this section plus the criteria in paragraphs (h)(1) and (h)(2) of this section.
- (1) An annual site visit by the State and correction of all identified sanitary defects. The system may substitute a voluntary Level 2 assessment by a party approved by the State for the State annual site visit in any given year.

(2) The system must have in place or adopt one or more additional enhancements to the water system barriers to contamination in paragraphs (h)(2)(i) through (h)(2)(v) of this section.

(i) Cross connection control, as approved by the State.

(ii) An operator certified by an appropriate State certification program or regular visits by a circuit rider certified by an appropriate State certification program.

(iii) Continuous disinfection entering the distribution system and a residual in the distribution system in accordance with criteria specified by the State.

(iv) Demonstration of maintenance of at least a 4-log removal or inactivation of viruses as provided for under § 141.403(b)(3).

(v) Other equivalent enhancements to water system barriers as approved by the State.

(i) *Seasonal systems.* (1) Beginning April 1, 2016, all seasonal systems must demonstrate completion of a State-approved start-up procedure, which may include a requirement for startup sampling prior to serving water to the public.

(2) A seasonal system must monitor every month that it is in operation unless it meets the criteria in paragraphs (i)(2)(i) through (iii) of this section to be eligible for monitoring less frequently than monthly beginning April 1, 2016, except as provided under paragraph (c) of this section.

(i) Seasonal systems monitoring less frequently than monthly must have an approved sample siting plan that designates the time period for monitoring based on site-specific considerations (e.g., during periods of highest demand or highest vulnerability to contamination). Seasonal systems must collect compliance samples during this time period.

(ii) To be eligible for quarterly monitoring, the system must meet the criteria in paragraph (g) of this section.

(iii) To be eligible for annual monitoring, the system must meet the criteria under paragraph (h) of this section.

(3) The State may exempt any seasonal system from some or all of the requirements for seasonal systems if the entire distribution system remains pressurized during the entire period that the system is not operating, except that systems that monitor less frequently than monthly must still monitor during the vulnerable period designated by the State.

(j) *Additional routine monitoring the month following a total coliform-positive sample.* Systems collecting samples on a quarterly or annual frequency must conduct additional routine monitoring the month following one or more total coliform-positive samples (with or without a Level 1 treatment technique trigger). Systems must collect at least three routine samples during the next month, except that the State may waive this requirement if the conditions of paragraph (j)(1), (2), or (3) of this section are met. Systems may either collect samples at regular time intervals throughout the month or may collect all required routine samples on a single day if samples are taken from different sites. Systems must use the results of additional routine samples in coliform treatment technique trigger calculations under §141.859(a).

(1) The State may waive the requirement to collect three routine samples the next month in which the system provides water to the public if the State, or an agent approved by the State, performs a site visit before the end of the next month in which the system provides water to the public. Although a sanitary survey need not be performed, the site visit must be sufficiently detailed to allow the State to determine whether additional monitoring and/or any corrective action is needed. The State cannot approve an employee of the system to perform this site visit, even if the employee is an agent approved by the State to perform sanitary surveys.

(2) The State may waive the requirement to collect three routine samples the next month in which the system provides water to the public if the State has determined why the sample was total coliform-positive and has established that the system has corrected the problem or will correct the problem before the end of the next month in which the system serves water to the public. In this case, the State must document this decision to waive the following month's additional monitoring requirement in writing, have it approved and signed by the supervisor of the State official who recommends such a decision, and make this document available to the EPA and public. The written documentation must describe the specific cause of the total coliform-positive sample and what action the system has taken and/or will take to correct this problem.

(3) The State may not waive the requirement to collect three additional routine samples the next month in which the system provides water to the public solely on the grounds that all repeat samples are total coliform-negative. If the State determines that the system has corrected the contamination problem before the system takes the set of repeat samples required in §141.858, and all repeat samples were total coliform-negative, the State may waive the requirement for additional routine monitoring the next month.

§ 141.855 Routine monitoring requirements for community water systems serving 1,000 or fewer people using only ground water.

(a) *General.* (1) The provisions of this section apply to community water systems using only ground water (except ground water under the direct influence of surface water, as defined in §141.2) and serving 1,000 or fewer people.

(2) Following any total coliform-positive sample taken under the provisions of this section, systems must comply with the repeat monitoring requirements and *E. coli* analytical requirements in § 141.858.

(3) Once all monitoring required by this section and § 141.858 for a calendar month has been completed, systems must determine whether any coliform treatment technique triggers specified in § 141.859 have been exceeded. If any trigger has been exceeded, systems must complete assessments as required by § 141.859.

(b) *Monitoring frequency for total coliforms.* The monitoring frequency for total coliforms is one sample/month, except as provided for under paragraphs (c) through (f) of this section.

(c) *Transition to subpart Y.* (1) All systems must continue to monitor according to the total coliform monitoring schedules under § 141.21 that were in effect on March 31, 2016, unless any of the conditions in paragraph (e) of this section are triggered on or after April 1, 2016, or unless otherwise directed by the State.

(2) Beginning April 1, 2016, the State must perform a special monitoring evaluation during each sanitary survey to review the status of the system, including the distribution system, to determine whether the system is on an appropriate monitoring schedule. After the State has performed the special monitoring evaluation during each sanitary survey, the State may modify the system's monitoring schedule, as necessary, or it may allow the system to stay on its existing monitoring schedule, consistent with the provisions of this section. The State may not allow systems to begin less frequent monitoring under the special monitoring evaluation unless the system has already met the applicable criteria for less frequent monitoring in this section.

(d) *Criteria for reduced monitoring.* (1) The State may reduce the monitoring frequency from monthly monitoring to no less than quarterly monitoring if the system is in compliance with

State-certified operator provisions and demonstrates that it meets the criteria in paragraphs (d)(1)(i) through (d)(1)(iii) of this section. A system that loses its certified operator must return to monthly monitoring the month following that loss.

(i) The system has a clean compliance history for a minimum of 12 months.

(ii) The most recent sanitary survey shows the system is free of sanitary defects (or has an approved plan and schedule to correct them and is in compliance with the plan and the schedule), has a protected water source and meets approved construction standards.

(iii) The system meets at least one of the following criteria:

(A) An annual site visit by the State that is equivalent to a Level 2 assessment or an annual Level 2 assessment by a party approved by the State and correction of all identified sanitary defects (or an approved plan and schedule to correct them and is in compliance with the plan and schedule).

(B) Cross connection control, as approved by the State.

(C) Continuous disinfection entering the distribution system and a residual in the distribution system in accordance with criteria specified by the State.

(D) Demonstration of maintenance of at least a 4-log removal or inactivation of viruses as provided for under § 141.403(b)(3).

(E) Other equivalent enhancements to water system barriers as approved by the State.

(e) *Return to routine monthly monitoring requirements.* Systems on quarterly monitoring that experience any of the events in paragraphs (e)(1) through (e)(4) of this section must begin monthly monitoring the month following the event. The system must continue monthly monitoring until it meets the reduced monitoring requirements in paragraph (d) of this section.

(1) The system triggers a Level 2 assessment or two Level 1 assessments in a rolling 12-month period.

(2) The system has an *E. coli* MCL violation.

(3) The system has a coliform treatment technique violation.

(4) The system has two subpart Y monitoring violations in a rolling 12-month period.

(f) *Additional routine monitoring the month following a total coliform-positive sample.* Systems collecting samples on a quarterly frequency must conduct additional routine monitoring the month following one or more total coliform-positive samples (with or without a Level 1 treatment technique trigger). Systems must collect at least three routine samples during the next month, except that the State may waive this requirement if the conditions of paragraph (f)(1), (2), or (3) of this section are met. Systems may either collect samples at regular time intervals throughout the month or may collect all required routine samples on a single day if samples are taken from different sites. Systems must use the results of additional routine samples in coliform treatment technique trigger calculations.

(1) The State may waive the requirement to collect three routine samples the next month in which the system provides water to the public if the State, or an agent approved by the State, performs a site visit before the end of the next month in which the system provides water to the public. Although a sanitary survey need not be performed, the site visit must be sufficiently detailed to allow the State to determine whether additional monitoring and/or any corrective action is needed. The State cannot approve an employee of the system to perform this site visit, even if the employee is an agent approved by the State to perform sanitary surveys.

(2) The State may waive the requirement to collect three routine samples the next month in which the system provides water to the public if the State has determined why the sample was total coliform-positive and has established that the system has corrected the problem or will correct the problem before the end of the next month in which the system serves water to the

public. In this case, the State must document this decision to waive the following month's additional monitoring requirement in writing, have it approved and signed by the supervisor of the State official who recommends such a decision, and make this document available to the EPA and the public. The written documentation must describe the specific cause of the total coliform-positive sample and what action the system has taken and/or will take to correct this problem.

(3) The State may not waive the requirement to collect three additional routine samples the next month in which the system provides water to the public solely on the grounds that all repeat samples are total coliform-negative. If the State determines that the system has corrected the contamination problem before the system takes the set of repeat samples required in § 141.858, and all repeat samples were total coliform-negative, the State may waive the requirement for additional routine monitoring the next month.

§ 141.856 Routine monitoring requirements for subpart H public water systems serving 1,000 or fewer people.

(a) *General.* (1) The provisions of this section apply to subpart H public water systems of this part serving 1,000 or fewer people.

(2) Following any total coliform-positive sample taken under the provisions of this section, systems must comply with the repeat monitoring requirements and *E. coli* analytical requirements in § 141.858.

(3) Once all monitoring required by this section and § 141.858 for a calendar month has been completed, systems must determine whether any coliform treatment technique triggers specified

in § 141.859 have been exceeded. If any trigger has been exceeded, systems must complete assessments as required by § 141.859.

(4) Seasonal systems. (i) Beginning April 1, 2016, all seasonal systems must demonstrate completion of a State-approved start-up procedure, which may include a requirement for start-up sampling prior to serving water to the public.

(ii) The State may exempt any seasonal system from some or all of the requirements for seasonal systems if the entire distribution system remains pressurized during the entire period that the system is not operating.

(b) *Routine monitoring frequency for total coliforms.* Subpart H systems of this part (including consecutive systems) must monitor monthly. Systems may not reduce monitoring.

(c) *Unfiltered subpart H systems.* A subpart H system of this part that does not practice filtration in compliance with subparts H, P, T, and W must collect at least one total coliform sample near the first service connection each day the turbidity level of the source water, measured as specified in § 141.74(b)(2), exceeds 1 NTU. When one or more turbidity measurements in any day exceed 1 NTU, the system must collect this coliform sample within 24 hours of the first exceedance, unless the State determines that the system, for logistical reasons outside the system's control, cannot have the sample analyzed within 30 hours of collection and identifies an alternative sample collection schedule. Sample results from this coliform monitoring must be included in determining whether the coliform treatment technique trigger in § 141.859 has been exceeded.

§ 141.857 Routine monitoring requirements for public water systems serving more than 1,000 people.

(a) *General.* (1) The provisions of this section apply to public water systems serving more than 1,000 persons.

(2) Following any total coliform-positive sample taken under the provisions of this section, systems must comply with the repeat monitoring requirements and *E. coli* analytical requirements in § 141.858.

(3) Once all monitoring required by this section and § 141.858 for a calendar month has been completed, systems must determine whether any coliform treatment technique triggers specified in § 141.859 have been exceeded. If any trigger has been exceeded, systems must complete assessments as required by § 141.859.

(4) Seasonal systems. (i) Beginning April 1, 2016, all seasonal systems must demonstrate completion of a State-approved start-up procedure, which may include a requirement for start-up sampling prior to serving water to the public.

(ii) The State may exempt any seasonal system from some or all of the requirements for seasonal systems if the entire distribution system remains pressurized during the entire period that the system is not operating.

(b) *Monitoring frequency for total coliforms.* The monitoring frequency for total coliforms is based on the population served by the system, as follows:

Total Coliform Monitoring Frequency for Public Water Systems Serving More Than 1,000 People

Population served	Minimum number of samples per month
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1,001 to 2,500.....	2
2,501 to 3,300.....	3
3,301 to 4,100.....	4
4,101 to 4,900.....	5
4,901 to 5,800.....	6
5,801 to 6,700.....	7
6,701 to 7,600.....	8
7,601 to 8,500.....	9
8,501 to 12,900.....	10
12,901 to 17,200.....	15
17,201 to 21,500.....	20
21,501 to 25,000.....	25
25,001 to 33,000.....	30
33,001 to 41,000.....	40
41,001 to 50,000.....	50
50,001 to 59,000.....	60
59,001 to 70,000.....	70
70,001 to 83,000.....	80
83,001 to 96,000.....	90
96,001 to 130,000.....	100
130,001 to 220,000.....	120
220,001 to 320,000.....	150
320,001 to 450,000.....	180
450,001 to 600,000.....	210
600,001 to 780,000.....	240
780,001 to 970,000.....	270
970,001 to 1,230,000.....	300
1,230,001 to 1,520,000.....	330
1,520,001 to 1,850,000.....	360
1,850,001 to 2,270,000.....	390
2,270,001 to 3,020,000.....	420
3,020,001 to 3,960,000.....	450
3,960,001 or more.....	480

(c) *Unfiltered subpart H systems.* A subpart H system of this part that does not practice filtration in compliance with subparts H, P, T, and W must collect at least one total coliform sample near the first service connection each day the turbidity level of the source water, measured as specified in § 141.74(b)(2), exceeds 1 NTU. When one or more turbidity measurements in any day exceed 1 NTU, the system must collect this coliform sample within 24 hours of the first exceedance, unless the State determines that the system, for logistical reasons

outside the system's control, cannot have the sample analyzed within 30 hours of collection and identifies an alternative sample collection schedule. Sample results from this coliform monitoring must be included in determining whether the coliform treatment technique trigger in § 141.859 has been exceeded.

(d) *Reduced monitoring.* Systems may not reduce monitoring, except for non-community water systems using only ground water (and not ground water under the direct influence of surface water) serving 1,000 or fewer people in some months and more than 1,000 persons in other months. In months when more than 1,000 persons are served, the systems must monitor at the frequency specified in paragraph (a) of this section. In months when 1,000 or fewer people are served, the State may reduce the monitoring frequency, in writing, to a frequency allowed under § 141.854 for a similarly situated system that always serves 1,000 or fewer people, taking into account the provisions in § 141.854(e) through (g).

§ 141.858 Repeat monitoring and *E. coli* requirements.

(a) *Repeat monitoring.* (1) If a sample taken under §§ 141.854 through 141.857 is total coliform-positive, the system must collect a set of repeat samples within 24 hours of being notified of the positive result. The system must collect no fewer than three repeat samples for each total coliform-positive sample found. The State may extend the 24-hour limit on a case-by-case basis if the system has a logistical problem in collecting the repeat samples within 24 hours that is beyond its control. Alternatively, the State may implement criteria for the system to use in lieu of case-by-case extensions. In the case of an extension, the State must specify how much time the system has to collect the repeat samples. The State cannot waive the requirement for a system to collect repeat samples in paragraphs (a)(1) through (a)(3) of this section.

(2) The system must collect all repeat samples on the same day, except that the State may allow a system with a single service connection to collect the required set of repeat samples over a three-day period or to collect a larger volume repeat sample(s) in one or more sample containers of any size, as long as the total volume collected is at least 300 ml.

(3) The system must collect an additional set of repeat samples in the manner specified in paragraphs (a)(1) through (a)(3) of this section if one or more repeat samples in the current set of repeat samples is total coliform-positive. The system must collect the additional set of repeat samples within 24 hours of being notified of the positive result, unless the State extends the limit as provided in paragraph (a)(1) of this section. The system must continue to collect additional sets of repeat samples until either total coliforms are not detected in one complete set of repeat samples or the system determines that a coliform treatment technique trigger specified in §141.859(a) has been exceeded as a result of a repeat sample being total coliform-positive and notifies the State. If a trigger identified in § 141.859 is exceeded as a result of a routine sample being total coliform-positive, systems are required to conduct only one round of repeat monitoring for each total coliform-positive routine sample.

(4) After a system collects a routine sample and before it learns the results of the analysis of that sample, if it collects another routine sample(s) from within five adjacent service connections of the initial sample, and the initial sample, after analysis, is found to contain total coliforms, then the system may count the subsequent sample(s) as a repeat sample instead of as a routine sample.

(5) Results of all routine and repeat samples taken under §§ 141.854 through 141.858 not invalidated by the State must be used to determine whether a coliform treatment technique trigger specified in § 141.859 has been exceeded.

(b) *Escherichia coli* (*E. coli*) testing. (1) If any routine or repeat sample is total coliform-positive, the system must analyze that total coliform-positive culture medium to determine if *E. coli* are present. If *E. coli* are present, the system must notify the State by the end of the day when the system is notified of the test result, unless the system is notified of the result after the State office is closed and the State does not have either an after-hours phone line or an alternative notification procedure, in which case the system must notify the State before the end of the next business day.

(2) The State has the discretion to allow a system, on a case-by-case basis, to forgo *E. coli* testing on a total coliform-positive sample if that system assumes that the total coliform-positive sample is *E. coli*-positive. Accordingly, the system must notify the State as specified in paragraph (b)(1) of this section and the provisions of § 141.63(c) apply.

§ 141.859 Coliform treatment technique triggers and assessment requirements for protection against potential fecal contamination.

(a) *Treatment technique triggers.* Systems must conduct assessments in accordance with paragraph (b) of this section after exceeding treatment technique triggers in paragraphs (a)(1) and (a)(2) of this section.

(1) Level 1 treatment technique triggers.

(i) For systems taking 40 or more samples per month, the system exceeds 5.0% total coliform-positive samples for the month.

(ii) For systems taking fewer than 40 samples per month, the system has two or more total coliform-positive samples in the same month.

(iii) The system fails to take every required repeat sample after any single total coliform-positive sample.

(2) Level 2 treatment technique triggers.

(i) An *E. coli* MCL violation, as specified in § 141.860(a).

(ii) A second Level 1 trigger as defined in paragraph (a)(1) of this section, within a rolling 12-month period, unless the State has determined a likely reason that the samples that caused the first Level 1 treatment technique trigger were total coliform-positive and has established that the system has corrected the problem.

(iii) For systems with approved annual monitoring, a Level 1 trigger in two consecutive years.

(b) *Requirements for assessments.* (1) Systems must ensure that Level 1 and 2 assessments are conducted in order to identify the possible presence of sanitary defects and defects in distribution system coliform monitoring practices. Level 2 assessments must be conducted by parties approved by the State.

(2) When conducting assessments, systems must ensure that the assessor evaluates minimum elements that include review and identification of inadequacies in sample sites; sampling protocol; sample processing; atypical events that could affect distributed water quality or indicate that distributed water quality was impaired; changes in distribution system maintenance and operation that could affect distributed water quality (including water storage); source and treatment considerations that bear on distributed water quality, where appropriate (e.g., small ground water systems); and existing water quality monitoring data. The system must conduct the assessment consistent with any State directives that tailor specific assessment elements with respect to the size and type of the system and the size, type, and characteristics of the distribution system.

(3) Level 1 Assessments. A system must conduct a Level 1 assessment consistent with State requirements if the system exceeds one of the treatment technique triggers in paragraph (a)(1) of this section.

(i) The system must complete a Level 1 assessment as soon as practical after any trigger in paragraph (a)(1) of this section. In the completed assessment form, the system must describe sanitary defects detected, corrective actions completed, and a proposed timetable for any corrective actions not already completed. The assessment form may also note that no sanitary defects were identified. The system must submit the completed Level 1 assessment form to the State within 30 days after the system learns that it has exceeded a trigger.

(ii) If the State reviews the completed Level 1 assessment and determines that the assessment is not sufficient (including any proposed timetable for any corrective actions not already completed), the State must consult with the system. If the State requires revisions after consultation, the system must submit a revised assessment form to the State on an agreed-upon schedule not to exceed 30 days from the date of the consultation.

(iii) Upon completion and submission of the assessment form by the system, the State must determine if the system has identified a likely cause for the Level 1 trigger and, if so, establish that the system has corrected the problem, or has included a schedule acceptable to the State for correcting the problem.

(4) Level 2 Assessments. A system must ensure that a Level 2 assessment consistent with State requirements is conducted if the system exceeds one of the treatment technique triggers in paragraph (a)(2) of this section. The system must comply with any expedited actions or additional actions required by the State in the case of an *E. coli* MCL violation.

(i) The system must ensure that a Level 2 assessment is completed by the State or by a party approved by the State as soon as practical after any trigger in paragraph (a)(2) of this section.

The system must submit a completed Level 2 assessment form to the State within 30 days after the system learns that it has exceeded a trigger. The assessment form must describe sanitary defects detected, corrective actions completed, and a proposed timetable for any corrective actions not already completed. The assessment form may also note that no sanitary defects were identified.

(ii) The system may conduct Level 2 assessments if the system has staff or management with the certification or qualifications specified by the State unless otherwise directed by the State.

(iii) If the State reviews the completed Level 2 assessment and determines that the assessment is not sufficient (including any proposed timetable for any corrective actions not already completed), the State must consult with the system. If the State requires revisions after consultation, the system must submit a revised assessment form to the State on an agreed-upon schedule not to exceed 30 days.

(iv) Upon completion and submission of the assessment form by the system, the State must determine if the system has identified a likely cause for the Level 2 trigger and determine whether the system has corrected the problem, or has included a schedule acceptable to the State for correcting the problem.

(c) *Corrective Action.* Systems must correct sanitary defects found through either Level 1 or 2 assessments conducted under paragraph (b) of this section. For corrections not completed by the time of submission of the assessment form, the system must complete the corrective action(s) in compliance with a timetable approved by the State in consultation with the system. The system must notify the State when each scheduled corrective action is completed.

(d) *Consultation.* At any time during the assessment or corrective action phase, either the water system or the State may request a consultation with the other party to determine the appropriate actions to be taken. The system may consult with the State on all relevant information that may impact on its ability to comply with a requirement of this subpart, including the method of accomplishment, an appropriate timeframe, and other relevant information.

§ 141.860 Violations.

(a) *E. coli MCL Violation.* A system is in violation of the MCL for *E. coli* when any of the conditions identified in paragraphs (a)(1) through (a)(4) of this section occur.

(1) The system has an *E. coli*-positive repeat sample following a total coliform-positive routine sample.

(2) The system has a total coliform-positive repeat sample following an *E. coli*-positive routine sample.

(3) The system fails to take all required repeat samples following an *E. coli*-positive routine sample.

(4) The system fails to test for *E. coli* when any repeat sample tests positive for total coliform.

(b) *Treatment technique violation.* (1) A treatment technique violation occurs when a system exceeds a treatment technique trigger specified in § 141.859(a) and then fails to conduct the required assessment or corrective actions within the timeframe specified in § 141.859(b) and (c).

(2) A treatment technique violation occurs when a seasonal system fails to complete a State-approved start-up procedure prior to serving water to the public.

(c) *Monitoring violations.* (1) Failure to take every required routine or additional routine sample in a compliance period is a monitoring violation.

(2) Failure to analyze for *E. coli* following a total coliform-positive routine sample is a monitoring violation.

(d) *Reporting violations.* (1) Failure to submit a monitoring report or completed assessment form after a system properly conducts monitoring or assessment in a timely manner is a reporting violation.

(2) Failure to notify the State following an *E. coli*-positive sample as required by § 141.858(b)(1) in a timely manner is a reporting violation.

(3) Failure to submit certification of completion of State-approved start-up procedure by a seasonal system is a reporting violation.

§ 141.861 Reporting and recordkeeping.

(a) *Reporting.* (1) *E. coli.*

(i) A system must notify the State by the end of the day when the system learns of an *E. coli* MCL violation, unless the system learns of the violation after the State office is closed and the State does not have either an after-hours phone line or an alternative notification procedure, in which case the system must notify the State before the end of the next business day, and notify the public in accordance with subpart Q of this part.

(ii) A system must notify the State by the end of the day when the system is notified of an *E. coli*-positive routine sample, unless the system is notified of the result after the State office is closed and the State does not have either an after-hours phone line or an alternative notification procedure, in which case the system must notify the State before the end of the next business day.

(2) A system that has violated the treatment technique for coliforms in § 141.859 must report the violation to the State no later than the end of the next business day after it learns of the violation, and notify the public in accordance with subpart Q of this part.

(3) A system required to conduct an assessment under the provisions of §141.859 of this part must submit the assessment report within 30 days. The system must notify the State in accordance with § 141.859(c) when each scheduled corrective action is completed for corrections not completed by the time of submission of the assessment form.

(4) A system that has failed to comply with a coliform monitoring requirement must report the monitoring violation to the State within 10 days after the system discovers the violation, and notify the public in accordance with subpart Q of this part.

(5) A seasonal system must certify, prior to serving water to the public, that it has complied with the State-approved start-up procedure.

(b) *Recordkeeping.* (1) The system must maintain any assessment form, regardless of who conducts the assessment, and documentation of corrective actions completed as a result of those assessments, or other available summary documentation of the sanitary defects and corrective actions taken under § 141.858 for State review. This record must be maintained by the system for a period not less than five years after completion of the assessment or corrective action.

(2) The system must maintain a record of any repeat sample taken that meets State criteria for an extension of the 24-hour period for collecting repeat samples as provided for under §141.858(a)(1) of this part.

PART 142 – NATIONAL PRIMARY DRINKING WATER REGULATIONS IMPLEMENTATION

21. The authority citation for part 142 continues to read as follows:

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

22. Section 142.14 is amended by revising paragraph (a)(1)(iii) and adding a new paragraph (a)(10) to read as follows:

§ 142.14 Records kept by States.

(a) ***

(1) ***

(iii) The analytical results, set forth in a form that makes possible comparison with the limits specified in §§ 141.63, 141.71, and 141.72 of this chapter and with the limits specified in subpart Y of this chapter.

(10) Records of each of the following decisions made pursuant to the provisions of subpart Y of part 141 must be made in writing and retained by the State.

(i) Records of the following decisions or activities must be retained for five years.

(A) Sections 141.858(a), 141.853(c)(2), 141.856(c), and 141.857(c) of this chapter - Any case-by-case decision to waive the 24-hour time limit for collecting repeat samples after a total coliform-positive routine sample, or to extend the 24-hour limit for collection of samples following invalidation, or for an unfiltered subpart H system of this part to collect a total coliform sample following a turbidity measurement exceeding 1 NTU.

(B) Sections 141.854(j) and 141.855(f) of this chapter – Any decision to allow a system to waive the requirement for three routine samples the month following a total coliform-positive sample.

The record of the waiver decision must contain all the items listed in those sections.

(C) Section 141.853(c) of this chapter – Any decision to invalidate a total coliform-positive sample. If the decision to invalidate a total coliform-positive sample as provided in §141.853(c)(1) of this chapter is made, the record of the decision must contain all the items listed in that section.

(D) Section 141.859 of this chapter – Completed and approved subpart Y assessments, including reports from the system that corrective action has been completed as required by § 141.861(a)(2) of this chapter.

(ii) Records of each of the following decisions must be retained in such a manner so that each system's current status may be determined:

(A) Section 141.854(e) of this chapter – Any decision to reduce the total coliform monitoring frequency for a non-community water system using only ground water and serving 1,000 or fewer people to less than once per quarter, as provided in § 141.854(e) of this chapter, including what the reduced monitoring frequency is. A copy of the reduced monitoring frequency must be provided to the system.

(B) Section 141.855(d) of this chapter – Any decision to reduce the total coliform monitoring frequency for a community water system serving 1,000 or fewer people to less than once per month, as provided in § 141.855(d) of this chapter, including what the reduced monitoring frequency is. A copy of the reduced monitoring frequency must be provided to the system.

(C) Section 141.857(d) of this chapter – Any decision to reduce the total coliform monitoring frequency for a non-community water system using only ground water and serving more than

1,000 persons during any month the system serves 1,000 or fewer people, as provided in § 141.857(d) of this chapter. A copy of the reduced monitoring frequency must be provided to the system.

(D) Section 141.858(b)(2) of this chapter – Any decision to allow a system to forgo *E. coli* testing of a total coliform-positive sample if that system assumes that the total coliform-positive sample is *E. coli*- positive.

23. Section 142.15 is amended by adding paragraph (c)(3) to read as follows:

§ 142.15 Reports by States.

(c) ***

(3) *Total coliforms under subpart Y.* A list of systems that the State is allowing to monitor less frequently than once per month for community water systems or less frequently than once per quarter for non-community water systems as provided in §§141.855 and 141.854 of this chapter, including the applicable date of the reduced monitoring requirement for each system.

24. Section 142.16 is amended by adding a new paragraph (q) to read as follows:

§ 142.16 Special primacy requirements.

(q) Requirements for States to adopt 40 CFR part 141 subpart Y – Revised Total Coliform Rule.

In addition to the general primacy requirements elsewhere in this part, including the requirements that State regulations be at least as stringent as federal requirements, an application for approval of a State program revision that adopts 40 CFR part 141, subpart Y, must contain the information specified in this paragraph (q).

(1) In their application to EPA for approval to implement the federal requirements, the primacy application must indicate what baseline and reduced monitoring provisions of 40 CFR part 141, subpart Y the State will adopt and must describe how they will implement 40 CFR part 141, subpart Y in these areas so that EPA can be assured that implementation plans meet the minimum requirements of the rule.

(2) The State's application for primacy for subpart Y must include a written description for each provision included in paragraphs (q)(2)(i) through (viii) of this section.

(i) Sample Siting Plans - The frequency and process used to review and revise sample siting plans in accordance with 40 CFR part 141, subpart Y to determine adequacy.

(ii) Reduced Monitoring Criteria – An indication of whether the State will adopt the reduced monitoring provisions of 40 CFR part 141, subpart Y. If the State adopts the reduced monitoring provisions, it must describe the specific types or categories of water systems that will be covered by reduced monitoring and whether the State will use all or a reduced set of the optional criteria. For each of the reduced monitoring criteria, both mandatory and optional, the State must describe how the criteria will be evaluated to determine when systems qualify.

(iii) Assessments and Corrective Actions – The process for implementing the new assessment and corrective action phase of the rule, including the elements in paragraphs (q)(2)(iii)(A) through (D) of this section.

(A) Elements of Level 1 and Level 2 assessments. This must include an explanation of how the State will ensure that Level 2 assessments provide a more detailed examination of the system (including the system's monitoring and operational practices) than do Level 1 assessments through the use of more comprehensive investigation and review of available information, additional internal and external resources, and other relevant practices.

(B) Examples of sanitary defects.

(C) Examples of assessment forms or formats.

(D) Methods that systems may use to consult with the State on appropriate corrective actions.

(iv) Invalidation of routine and repeat samples collected under 40 CFR part 141, subpart Y – The criteria and process for invalidating total coliform and *E. coli*-positive samples under 40 CFR part 141, subpart Y. This description must include criteria to determine if a sample was improperly processed by the laboratory, reflects a domestic or other non-distribution system plumbing problem or reflects circumstances or conditions that do not reflect water quality in the distribution system.

(v) Approval of individuals allowed to conduct Level 2 assessments under 40 CFR part 141, subpart Y – The criteria and process for approval of individuals allowed to conduct Level 2 assessments under 40 CFR part 141, subpart Y.

(vi) Special monitoring evaluation – The procedure for performing special monitoring evaluations during sanitary surveys for ground water systems serving 1,000 or fewer people to determine whether systems are on an appropriate monitoring schedule.

(vii) Seasonal systems – How the State will identify seasonal systems, how the State will determine when systems on less than monthly monitoring must monitor, and what start-up provisions seasonal system must meet under 40 CFR part 141, subpart Y.

(viii) Additional criteria for reduced monitoring – How the State will require systems on reduced monitoring to demonstrate:

(A) Continuous disinfection entering the distribution system and a residual in the distribution system.

(B) Cross connection control.

(C) Other enhancements to water system barriers.

(ix) Criteria for extending the 24-hour period for collecting repeat samples. – Under §§ 141.858(a) and 141.853(c)(2) of this chapter, criteria for systems to use in lieu of case-by-case decisions to waive the 24-hour time limit for collecting repeat samples after a total coliform-positive routine sample, or to extend the 24-hour limit for collection of samples following invalidation. If the State elects to use only case-by-case waivers, the State does not need to develop and submit criteria.

25. Section 142.63 is amended by revising paragraph (b) to read as follows:

§ 142.63 Variances and exemptions from the maximum contaminant level for total coliforms.

(b) EPA has stayed this section as it relates to the total coliform MCL of §141.63(a) of this chapter for systems that demonstrate to the State that the violation of the total coliform MCL is due to a persistent growth of total coliforms in the distribution system rather than fecal or pathogenic contamination, a treatment lapse or deficiency, or a problem in the operation or maintenance of the distribution system. This stay is applicable until March 31, 2016, at which time the total coliform MCL is no longer applicable.