

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 9, 141, and 142

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RIN 2040-AD17

National Primary Drinking Water Regulations: Filter Backwash Recycling Rule

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: In this document, EPA is finalizing the Filter Backwash Recycling Rule (FBRR). The purpose of the FBRR is to further protect public health by requiring public water systems (PWSs), where needed, to institute changes to the return of recycle flows to a plant's treatment process that may otherwise compromise microbial control. Today's final rule addresses a statutory requirement of the 1996 Safe Drinking Water Act (SDWA) Amendments to promulgate a regulation which

“governs” the recycling of filter backwash water within the treatment process of PWSs.

DATES: This regulation is effective August 7, 2001. As discussed in the supplementary information section and consistent with sections 1412(b)(10) and 1445 of SDWA, regulated entities must comply with this rule starting December 8, 2003. For judicial review purposes, this final rule is promulgated as of 1 p.m. eastern time on June 8, 2001.

ADDRESSES: Public comments, the comment/response document, applicable **Federal Register** documents, other major supporting documents, and a copy of the index to the public docket for this rulemaking are available for review at EPA's Office of Water Docket: Docket W-99-10 Final Filter Backwash Recycling Rule, 401 M Street, SW., Rm. EB57, Washington, DC 20460 from 9:00 a.m. to 4:00 p.m., Eastern Time, Monday through Friday, excluding federal holidays. For access to docket materials or to schedule an appointment, please call (202) 260-3027.

FOR FURTHER INFORMATION CONTACT: For technical inquiries, contact Jeffery Robichaud, Office of Ground Water and Drinking Water (4607), U.S. Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone (202) 260-2568. For general information contact the Safe Drinking Water Hotline, Telephone (800) 426-4791. The Safe Drinking Water Hotline is open Monday through Friday, excluding Federal holidays, from 9:00 a.m. to 5:30 p.m. Eastern Time.

SUPPLEMENTARY INFORMATION: *Regulated entities.* Entities potentially regulated by the FBRR are public water systems that use surface water or ground water under the direct influence of surface water (GWUDI), practice conventional or direct filtration, and recycle spent filter backwash, thickener supernatant, or liquids from dewatering processes. Regulated categories and entities include:

Category	Examples of regulated entities
Industry	Public Water Systems that use surface water or ground water under the direct influence of surface water.
State, Local, Tribal or Federal Governments	Public Water Systems that use surface water or ground water under the direct influence of surface water.

This table is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be regulated by the FBRR. This table lists the types of entities that EPA is now aware could potentially be regulated by this rule. Other types of entities not listed in this table could also be regulated. To determine whether your facility is regulated by this action, you should carefully examine the definition of PWS in § 141.2 of title 40 of the Code of Federal Regulations and § 141.76 of today's final rule. If you have questions regarding the applicability of the FBRR to a particular entity, consult the person listed in the preceding section entitled **FOR FURTHER INFORMATION CONTACT.**

List of abbreviations/acronyms used in this document:

- AWWA American Water Works Association
- AWWSCo American Water Works Service Company
- °C Degrees Celsius
- CCR Consumer Confidence Report
- CFR Code of Federal Regulations
- CPE Comprehensive Performance Evaluation
- DAF Dissolved Air Flotation
- EPA Environmental Protection Agency

- ESWTR Enhanced Surface Water Treatment Rule
- FBRR Filter Backwash Recycling Rule
- FR Federal Register
- gpm Gallons per Minute
- GWUDI Ground Water Under the Direct Influence of Surface Water
- HRRCA Health Risk Reduction and Cost Analysis
- ICR Information Collection Request
- IESWTR Interim Enhanced Surface Water Treatment Rule
- IRFA Initial Regulatory Flexibility Analysis
- LT1ESWTR Long Term 1 Enhanced Surface Water Treatment Rule
- MCLG Maximum Contaminant Level Goal
- NDWAC National Drinking Water Advisory Council
- NPDWR National Primary Drinking Water Regulation
- NODA Notice of Data Availability
- NTTAA National Technology Transfer and Advancement Act
- OMB Office of Management and Budget
- PBMS Performance-based Measurement System
- PRA Paperwork Reduction Act
- PWS Public Water System
- RFA Regulatory Flexibility Act
- SAB Science Advisory Board

- SBA Small Business Administration
- SBAR Small Business Advocacy Review
- SBREFA Small Business Regulatory Enforcement Fairness Act of 1996
- SDWA Safe Drinking Water Act
- SDWIS Safe Drinking Water Information System
- UMRA Unfunded Mandates Reform Act

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I. Summary

A. Why Is EPA Promulgating the Filter Backwash Recycling Rule (FBRR)?

When a facility recycles filter backwash water, it reintroduces contaminants back into treatment processes. Poor recycle practices can degrade influent water quality and impair treatment process performance. The 1996 Amendments to the Safe Drinking Water Act (SDWA) require EPA to promulgate a regulation that "governs" the recycle of filter backwash water within a treatment plant (42 U.S.C. 300g-1(b)(14)). Today's final rule addresses filter backwash water and two additional recycle streams of concern, sludge thickener supernatant and liquids from dewatering processes. The Agency believes that establishing such a regulation will improve performance at filtration plants by reducing the opportunity for recycle practices to adversely affect plant performance in a way that would allow microbes such as *Cryptosporidium* to pass through into finished drinking water.

B. What Are Filter Backwash Water, Sludge Thickener Supernatant, and Liquids From Dewatering Processes?

Throughout today's final rule, when the word recycle is used as a noun it refers to the three recycle streams (filter backwash water, sludge thickener supernatant, and liquids from dewatering processes) regulated under the FBRR.

Filter backwashing is an integral part of treatment plant operation. When filters need to be cleaned, water must be returned back up through the filtration media with sufficient force to separate particles from the filter media. The resulting water which was pushed back through the filter in the cleaning process is referred to as filter backwash water or spent filter backwash water. It contains many of the particles that were trapped in the filter during operation, including coagulants, metals, and microbes such as *Cryptosporidium*. Several studies have documented a range of *Cryptosporidium* oocysts concentrations in spent filter backwash from non-detects to over 15,000 oocysts/100 L, (EE&T, 1999).

Sedimentation basins and clarifiers are constructed to remove particles from a treatment process through gravity settling. When these units are employed to treat recycled water, the "clear water" that exits the units after particles have been allowed to settle out is called sludge thickener supernatant. While the sludge at the bottom of sedimentation basins and clarifiers contain the majority of the *Cryptosporidium* oocysts

entering a unit, recent research has documented a range of concentrations of *Cryptosporidium* oocysts in thickener supernatant from 82 to 420 oocysts/100 L (EE&T, 1999).

Finally, some filtration plants employ dewatering processes to remove water from waste solids in order to reduce the solids volume to be disposed. This "sludge" typically comes from sedimentation basins and clarifiers and contains only one to two percent solids. The dewatering units press or centrifuge the sludge, removing liquids from solids, which increases the solids volume up to 90 percent. The liquids that are removed are referred to as liquids from dewatering processes. Since nearly all particles and solids are removed in sludge or slurry form from a treatment plant, the sludge or slurry will contain a substantial amount of the *Cryptosporidium* oocysts which have entered the plant since the dewatering unit was last cleaned. If this sludge or slurry is dewatered, there exists significant potential that the liquids from dewatering may contain elevated levels of *Cryptosporidium* oocysts. Although the Agency is unaware of specific effluent liquid oocyst data from dewatering processes, influent slurries (consisting of sedimentation basin sludges) have been shown to contain a range of *Cryptosporidium* oocyst concentrations, even as high as 2,600 oocysts/100 L (EE&T, 1999).

It should be noted that process solids recycle flows from softening and contact clarification units are not covered by today's final FBRR. However, if softening systems or contact clarification systems recycle any of the three recycle flows covered by the FBRR (filter backwash water, sludge thickener supernatant, and liquids from dewatering processes) then they must meet the requirements of the FBRR for these three recycle flows.

C. What Is *Cryptosporidium*?

Cryptosporidium is a protozoan parasite found in humans, many other mammals and also in birds, fish and reptiles. It is common in the environment and widely found in surface water supplies (Rose, 1988; LeChevallier and Norton, 1995; Atherholt et al., 1998; EPA, 2000a). In the infected animal, the parasite multiplies in the gastrointestinal tract. The animal then excretes oocysts of the parasite in its feces. These oocysts are tiny spore-like organisms 4 to 6 microns in diameter (too small to be seen without a microscope) which contain the sporozoites (infective form). The oocysts of *Cryptosporidium* are very resistant to adverse factors in the

environment and can survive dormant for months in cool, dark, moist soil or for up to a year in clean water. When ingested by another animal, they can reproduce in the intestinal tract and start a new cycle of cryptosporidiosis illness. Cryptosporidiosis is primarily a waterborne disease, but cryptosporidiosis has also been transmitted by consumption of contaminated food, unhygienic diaper changing practices (and other person-to-person contact), and contact with young farm animals.

Cryptosporidium oocysts are relatively resistant at normal temperatures and are not easily killed by commonly used disinfectants. Oocyst infectivity appears to persist under normal temperatures, although oocysts may lose infectivity if sufficiently cooled or heated (EPA, 2000a). For example, Fayer (1994) discovered that cleaned oocysts in distilled water heated to 72.4 °C for 1 minute and to 64.2 °C for two minutes were not infective to mice. Fayer and Nerad (1996) found that cleaned oocysts in distilled water cooled to -20 °C for eight hours and 70 °C for 1 hour were not infective to mice. However, oocysts may remain viable after freezing (Fayer and Nerad, 1996). The oocysts are relatively unaffected by chlorine and chloramines in the concentrations that are used for drinking water treatment. They are also resistant to the effects of 60 percent alcohol and many disinfectants commonly used in the home or animal husbandry.

D. What Are the Health Concerns Associated With *Cryptosporidium*?

When someone is infected with *Cryptosporidium*, symptoms can include watery diarrhea, stomach cramps, nausea, loss of appetite, and a mild fever. This disease is called cryptosporidiosis and is a major cause of reported waterborne disease outbreaks from rivers, lakes, waterparks, and swimming pools. The symptoms of cryptosporidiosis begin an average of seven days after infection. Persons with a normal, healthy immune system can expect their illness to last for two weeks or less, with constant or intermittent diarrhea. Even after symptoms cease, an individual can still pass *Cryptosporidium* in the stool for up to two months and may be a source of infection for others. Cryptosporidiosis is not treatable with antibiotics so prevention of infection is critical. People with weakened immune systems (those with HIV/AIDS, on cancer chemotherapy, or those who have received organ transplants) may have cryptosporidiosis for a longer period of

time, and it can be life-threatening. Small children, pregnant women, or the elderly infected with cryptosporidiosis can quickly become severely dehydrated.

E. Does This Regulation Apply to My Water System?

Today's final rule applies to all public water systems that:

- Use surface water or ground water under the direct influence of surface water (GWUDI);
- Utilize direct or conventional filtration processes; and
- Recycle spent filter backwash water, sludge thickener supernatant, or liquids from dewatering processes.

F. How Will This Regulation Protect Public Health?

EPA has determined that the presence of microbiological contaminants is a health concern. If finished water supplies contain microbiological contaminants, disease outbreaks may result. Of the 12 waterborne cryptosporidiosis outbreaks that have occurred at drinking water systems since 1984, three (Carrollton, GA, 1987; Talent, OR, 1992; and Milwaukee, WI, 1993) were linked to contaminated drinking water from water utilities where waste stream recycle was identified as a possible cause (Craun, 1998; EPA, 2000a). The largest of the known outbreaks occurred in Milwaukee and was responsible for over 400,000 illnesses and 50 deaths (Hoxie, et al., 1997; MacKenzie et al., 1994); other known outbreaks have occurred in smaller communities and have involved many fewer people.

The Surface Water Treatment Rule (SWTR) and Interim Enhanced Surface Water Treatment Rule (IESWTR) (63 FR 69478, December 16, 1998) set enforceable drinking water treatment technique requirements to reduce the risk of waterborne microbiological disease including *Cryptosporidium* from surface water. Today's final rule provides further necessary protection against *Cryptosporidium* for systems that practice recycle.

Today's rule ensures that the 2-log *Cryptosporidium* removal requirement established in the IESWTR and proposed in the Long Term 1 Enhanced Surface Water Treatment Rule (LT1ESWTR) (65 FR 19046, April 10, 2000) is not jeopardized by recycle practices. The rule requires (with some exceptions) that recycle be returned through the processes of a system's existing conventional or direct filtration (as defined in § 141.2 of the CFR) that the Agency has recognized capable of achieving 2-log (99 percent)

Cryptosporidium removal. Today's rule also ensures that systems and States will have the recycle flow information necessary to evaluate whether site-specific recycle practices may adversely affect the ability of systems to achieve 2-log *Cryptosporidium* removal. Surges of recycle flow returned to the treatment plant may adversely affect treatment systems by creating hydraulically overloaded conditions (when plants exceed design capacity or State-approved operating capacity) that can lower performance of individual units within a treatment plant resulting in lowered *Cryptosporidium* removal efficiency.

II. Background

A. What Is the Statutory Authority for the FBRR?

The Safe Drinking Water Act (SDWA or the Act), as amended in 1986, requires EPA to publish a maximum contaminant level goal (MCLG) for each contaminant which, in the judgement of EPA, "may have any adverse effect on the health of persons and which is known or anticipated to occur in public water systems" (Section 1412(b)(3)(A)). MCLGs are to be set at a level at which "no known or anticipated adverse effect on the health of persons occur and which allows an adequate margin of safety" (Section 1412(b)(4)).

The Act was again amended in August 1996, resulting in the renumbering and augmentation of certain sections with additional statutory language. New sections were added establishing new drinking water requirements. Section 1412(b)(14) requires EPA to promulgate a regulation to govern the recycling of filter backwash water within the treatment process of a public water system. The Amendments require EPA to promulgate such a regulation no later than four years after the date of the enactment of the SDWA Amendments of 1996 unless this type of recycling has been addressed by EPA's Enhanced Surface Water Treatment Rule prior to the deadline.

B. What Is the Regulatory History for the FBRR?

The practice of filter backwash recycling has not previously been addressed in drinking water rules promulgated by the Agency. As noted earlier, the 1996 Amendments to the SDWA, required EPA to promulgate a regulation governing the recycling of filter backwash water. The Agency first presented information regarding filter backwash practices, data, and health risks in the November 3, 1997, Interim

Enhanced Surface Water Treatment Rule Notice of Data Availability (NODA) (62 FR 59486). In this NODA, EPA indicated that while both the SWTR and forthcoming IESWTR contained treatment technique requirements designed to address microbial pathogens such as *Cryptosporidium*, neither the SWTR or IESWTR addressed filter backwash recycling practices. In the NODA, EPA indicated that it did not plan to include separate provisions for regulating recycling of filter backwash water in the IESWTR, but planned to develop a regulation to address filter backwash recycling in conjunction with the Long Term 1 Enhanced Surface Water Treatment Rule (LT1ESWTR). The proposed LT1ESWTR and FBRR were published on April 10, 2000 (65 FR 19046).

C. How Were Stakeholders Involved in the Development of the FBRR?

The Agency initially conducted a broad literature search to gather research papers and information on the occurrence of *Cryptosporidium* and other materials in recycle flows. The literature search also sought information on how recycling practices may impact plant efficiency. The Agency worked with American Water Works Association (AWWA), the American Water Works Service Company (AWWSCo.), and Cincinnati Water Works to develop twelve issue papers on commonly generated recycle flows. These papers are found in the docket of today's final rule (EE&T, 1999).

EPA began outreach efforts to develop the FBRR in the summer of 1998. Two public stakeholder meetings, announced in the **Federal Register**, were held on July 22–23, 1998, in Lakewood, Colorado, and on March 3–4, 1999, in Dallas, Texas. In addition, EPA held several formal and informal meetings with stakeholders, trade associations, and environmental groups. Small entity representatives also contributed valuable input as part of the Small Business Regulatory Enforcement Fairness Act (SBREFA) panel process. The FBRR SBREFA panel was initiated in April of 1998 and officially convened in August of 1998. The panel's recommendations were incorporated into today's final rule.

During rule development EPA considered a range of different options. In addition to those found in the proposed rule, EPA also considered mandatory treatment of recycle streams and a ban on all recycle flows, but ultimately did not select these options. EPA determined that the rule would apply to the three largest recycle flows at treatment plants (spent filter

backwash, sludge thickener supernatant, and liquids from dewatering processes), which constitute 98 percent of recycle flow at an average system.

In early June 1999, EPA mailed an informal draft of the FBRR preamble to approximately 100 stakeholders who attended either of the public stakeholder meetings. Members of trade associations and the SBREFA panel also received the draft preamble. EPA received valuable comments and stakeholder input from 15 State representatives, trade associations, environmental interest groups, and individual stakeholders.

During the comment period for today's rule, the Agency held a public meeting in Washington, DC on April 14, 2000. Additionally, the proposed rule was either presented or discussed in nearly 50 meetings across the U.S. (EPA, 2000i). Finally, EPA requested stakeholder comments by mailing approximately 200 copies of the proposed rule to stakeholders requesting comment. EPA received 67 comments from a variety of stakeholders including States, municipalities, Tribes, elected officials, consultants, trade groups, and private industry. These comments were reviewed and evaluated while developing today's final rule. Responses to all of the comments are found in EPA's Response to Comment Document for the FBRR (EPA, 2000j).

D. What Did the April 10, 2000 Proposal Contain?

The April 10, 2000 proposal (65 FR 19046) contained the Filter Backwash Recycling Rule provisions as well as the LT1ESWTR provisions. The proposed rulemaking package was entitled, "The Long Term 1 Enhanced Surface Water Treatment and Filter Backwash Rule; Proposed Rule" (EPA, 2000b). The Agency intends to promulgate the LT1ESWTR in a future **Federal Register** announcement, separate from today's final rule. The FBRR provisions of the proposal applied to all surface water and GWUDI systems which recycle regardless of population served. The proposal included the following requirements:

- Spent filter backwash water, sludge thickener supernatant, and liquids from dewatering processes were required to be recycled prior to the point of primary coagulant addition unless the State specified an alternative location;
- Conventional filtration systems with 20 or fewer filters that recycle spent filter backwash water, sludge thickener supernatant, or liquids from dewatering processes without treatment or equalization were required to perform a one month, one-

time recycle self assessment. The proposed self assessment required hydraulic flow monitoring and certain data to be reported to the State. Upon review of these data, the State could require that modifications be made to the recycle practice in order to protect public health; and

- Direct filtration systems recycling to the treatment process were required to provide detailed recycle treatment information to the State. Upon review of this data, the State could require that modifications be made to the recycle practice in order to protect public health.

These three requirements have been modified in today's final FBRR as described in the following section.

III. Discussion of Today's Filter Backwash Recycle Rule Requirements

A. Where Does the FBRR Specify That Recycle Must Be Returned?

1. What Does Today's Rule Require?

The Agency's goal is to address risks associated with certain recycle practices in the least burdensome, most effective, and simplest means possible. Accordingly, today's final rule requires that recycled filter backwash water, sludge thickener supernatant, and liquids from dewatering processes must be returned to a location such that all processes of a system's conventional or direct filtration, as defined in § 141.2, are employed. Systems may apply to the State if they want to recycle at an alternate location.

2. What Was the Rationale and Basis for the Proposed Requirement?

The Agency proposed that spent filter backwash water, sludge thickener supernatant, and liquids from dewatering process be recycled prior to the point of primary coagulant addition unless the State specified an alternative location. In establishing this proposed requirement, EPA had two goals in mind. First, the Agency believes it is important that recycle practices be conducted in a manner that does not upset the chemical treatment and coagulation process vital to the performance and contaminant removal capability of a filtration plant. Second, the Agency also believes treatment plants must assure that *Cryptosporidium* oocysts in recycled water, as well as source water, receive the full benefit of well-operated treatment processes to achieve at least 2-log *Cryptosporidium* removal.

As indicated in the proposal, close to 80 percent of the systems which recycle, currently return recycle prior to the rapid mix unit and coagulation stage of

the treatment plant. Studies from many researchers (Patania et al., 1995; Edzwald and Kelly, 1998; Bellamy et al., 1993; Conley, 1965; Robeck et al., 1964; and Trussell et al., 1980) indicate that proper coagulation is paramount to optimal performance of treatment plants. In fact, pilot scale work performed by Dugan et al. (1999) showed that coagulation has a significant influence on the log removal of *Cryptosporidium*.

The ability for conventional and direct filtration plants to remove *Cryptosporidium* under appropriate coagulation conditions was demonstrated through eight studies (Patania et al., 1995; Nieminski and Ongerth, 1995; Ongerth and Pecoraro, 1995; LeChevallier and Norton, 1992; LeChevallier et al., 1991; Foundation for Water Research, 1994; Kelly et al., 1995; and West et al., 1994) that were described in greater detail in the proposal for today's final rule (EPA, 2000b). These eight studies demonstrated that conventional and direct filtration plants which employed coagulation, flocculation, sedimentation (in conventional filtration only), and filtration steps had the ability to achieve at least 2-log removal of *Cryptosporidium* when meeting specific turbidity limits. These studies formed the basis for the Agency's development of turbidity limits (0.3 NTU 95 percent of the time and a 1 NTU maximum) associated with the 2-log treatment technique in the IESWTR and the proposed LT1ESWTR. As noted earlier, none of the studies evaluated the practice of recycling on treatment performance.

In order to minimize the impacts of recycle on chemical treatment, minimize hydraulic disruption within the treatment processes due to recycle, and provide the appropriate level of treatment necessary to achieve at least 2-log removal of *Cryptosporidium* in recycle flows, the Agency believed it necessary to include as part of the proposed FBRR, a specific recycle return location requirement, while also allowing systems the ability to establish alternate recycle locations as approved by the State.

3. What Major Comments Were Received on the Proposal?

Many commenters agreed with the proposal and noted that requiring recycle to be returned prior to the point of primary coagulant addition was appropriate. Several others noted that recycle should be allowed concurrent with the point of primary coagulant addition. Still others, most notably EPA's Science Advisory Board (SAB),

indicated that because of the site-specific characteristics of recycle, defining a single acceptable recycle return location was inappropriate since, in some circumstances, it could reduce the performance of the treatment system. Finally, a few commenters expressed concern regarding workload implications for States if too many requests for alternate recycle locations are received.

4. What Was the Basis for Revising the Proposal?

After evaluating the data submitted by commenters, EPA believes that the goal of this rule can be achieved more efficiently by slightly modifying the return location requirement. Rather than requiring recycle to be returned to a specific location, today's final rule requires recycle flows to pass through all processes of the system's representative treatment as defined in § 141.2 in order for conventional and direct filtration systems which recycle to maintain 2-log *Cryptosporidium* removal credit. For most systems, this requirement would allow the return of recycle concurrent with the point of primary coagulant addition. Today's final rule continues to allow States the opportunity to approve alternative recycle return locations for systems on a system-specific basis. Conventional filtration is defined in § 141.2 of the Code of Federal Regulations as a series of processes including coagulation, flocculation, sedimentation, and filtration resulting in substantial particle removal. Direct filtration is defined in § 141.2 of the Code of Federal Regulations as a series of processes including coagulation and filtration but excluding sedimentation resulting in substantial particle removal. As noted earlier, the ability for conventional and direct filtration plants to remove *Cryptosporidium* has been demonstrated in many studies. These studies demonstrated that conventional and direct filtration plants which employed coagulation, flocculation, sedimentation (in conventional filtration only), and filtration processes, had the ability to achieve 2-log removal of *Cryptosporidium* while meeting specific turbidity limits. EPA firmly believes these studies demonstrate a minimum of 2-log *Cryptosporidium* removal only when water passes through all processes of conventional or direct filtration treatment. Some studies have shown that when recycle is performed properly, namely when recycle is returned through all processes of the plant's existing treatment system and normal plant operations are not disrupted with hydraulic surges or

increased overall plant flow, the return of recycle does not perceptively impair plant treatment with respect to *Cryptosporidium* or turbidity removal (Levesque et al., 1999 and Cornwell and MacPhee, 2001). Because continuing to ensure at least 2-log *Cryptosporidium* removal is the goal of this provision, EPA believes it appropriate to require that recycle be returned at least through existing processes which the Agency has determined to have the ability to achieve 2-log *Cryptosporidium* removal, instead of requiring that recycle be returned to a discrete location.

The Agency continues to recognize that some systems may be able to achieve 2-log or higher *Cryptosporidium* removal when recycling to other locations within the treatment plant. Therefore, the final rule continues to include a provision that States may approve alternate recycling locations for systems on a case-by-case basis. However, the Agency dropped an explicit requirement in the proposal that systems must apply to the State for approval of the change in recycle location before the system implements it, as the Agency believes that such a requirement is implicit in the regulatory language for today's final rule, and unnecessary as systems are unlikely to make a change to their location without approval from the State.

B. What Reporting Does the FBRR Require of Conventional Filtration Systems That Recycle?

1. What Does Today's Rule Require?

The Agency's goal is to address risks associated with recycle practices in the least burdensome, most effective, and simplest means possible. Accordingly, today's final rule requires that systems that practice conventional filtration and recycle spent filter backwash, sludge thickener supernatant, or liquids from dewatering processes, notify the State in writing that they practice recycle. When notifying the State, systems must also provide the following information:

- A plant schematic showing the origin of all recycle flows, the hydraulic conveyance used to transport them, and the location where they are recycled back into the plant; and
- Typical recycle flow in gallons per minute (gpm), highest observed plant flow experienced in the previous year (gpm), design flow for the treatment plant (gpm), and the State-approved operating capacity for the plant where the State has made such determinations.

Additionally, systems must collect and maintain the following information for review by the State, which may, after

evaluating the information, require a system to modify their recycle location or recycle practices:

- (1) Copy of the recycle notification and information submitted to the State;
- (2) List of all recycle flows and the frequency with which they are returned;
- (3) Average and maximum backwash flow rate through the filters and the average and maximum duration of the filter backwash process in minutes;
- (4) Typical filter run length and a written summary of how filter run length is determined (headloss, turbidity, time etc.);
- (5) The type of treatment provided for the recycle flow; and
- (6) Data on the physical dimensions of the equalization and/or treatment units, typical and maximum hydraulic loading rates, type of treatment chemicals used and average dose and frequency of use, and frequency at which solids are removed from treatment units where such units are used.

These requirements are identical to the requirements for direct filtration systems that recycle, as described in Section III.C. They are discussed in separate preamble sections because in the proposed rule, separate and distinct requirements for the two types of systems were proposed.

2. What Was the Rationale and Basis for the Proposed Requirement?

The Agency proposed that conventional filtration systems with fewer than 20 filters that do not provide treatment or equalization of their recycle streams would be required to develop a flow monitoring plan for submittal and approval by the State, conduct a month of flow monitoring, and develop and submit a self-assessment report to the State. The State would then be required to make a determination of whether modifications to a system's recycle practice should be required.

This component was designed to assist States in addressing the potential negative impact of hydraulic surge on treatment performance. The first component of today's final rule requires that recycle flows proceed through all steps of the treatment processes to ensure 2-log removal of *Cryptosporidium*. However, hydraulic surge can still upset treatment performance even when recycle is treated by all necessary steps of a treatment process (e.g., surges that cause hydraulic flow to exceed design or operating capacity).

Because of the high volume of water and short duration of a filter backwash recycle event (typically about 15 minutes long), a large volume of water

may surge through the treatment plant. This hydraulic surge can potentially overload treatment capability by challenging the ability of each process within a system including the filters. Some studies have demonstrated (Glasgow and Wheatley, 1998; McTigue *et al.*, 1998; and Myers *et al.*, 2000) that increasing loading rates through surges to filters can have an adverse effect on finished water quality. McTigue *et al.*, reported that when filter loading rates in a pilot plant were doubled from 2 gpm to 4 gpm instantaneously, *Cryptosporidium* counts in finished water jumped from non detect to 18 oocysts/100 L. When filter loading rates were doubled from 4 gpm to 8 gpm instantaneously, *Cryptosporidium* counts in finished water jumped from non detect to 50 oocysts/100L, resulting in a reduction in performance from 5-log *Cryptosporidium* removal to 3.5-log *Cryptosporidium* removal. Pilot work completed by Myers *et al.*, showed that when hydraulic surges occurred, particle counts increased. When hydraulic flow was instantaneously increased from 2 gpm to 3 gpm, particle counts rose from 17 particles/mL to 27 particles/mL. When the flow was raised from 2 gpm to 4 gpm, particle counts rose from 17 particles/mL to 36 particles/mL. Many commenters to the IESWTR noted that increased loading rates to filters (in excess of approved design rates) would contribute to poor performance of filters (EPA, 1998l).

Although hydraulic surging can have an adverse effect, systems that practice equalization or treatment of their recycle streams can mitigate the effect that recycle may have on the performance of the treatment systems. Limited data (Cornwell and Lee, 1996) have shown that equalization of recycle streams minimizes the risk of hydraulic upset. Proper equalization can serve to avoid abrupt changes in the flow rates and the water quality. Several studies have recommended maintaining recycle flow at or below 10 percent of the plant flow (Cornwell and Lee, 1994; McGuire, 1997; Pederson and Calhoun, 1995; and Levesque *et al.*, 1999).

Treatment reduces the number of microbial constituents a recycle flow may reintroduce into the primary treatment process and therefore, reduce the risk associated with passing oocysts if hydraulic surges occur. Work by a variety of individuals (Grubb and Arnold, 1997; Levesque *et al.*, 1999; and Parker *et al.*, 1999;) has demonstrated the utility of treatment of recycle streams prior to being returned to the primary treatment plant. In addition, as indicated previously, some studies have shown that when recycle is performed

in accordance with the requirements of the FBRR, *Cryptosporidium* removal is not impaired, even without separate treatment of recycle streams.

Given the variety and site-specific nature of recycle practices throughout the country, the Agency believed it necessary to require conventional filtration systems to notify States that they practice recycle, and provide information the State could utilize to evaluate whether a treatment plant may be susceptible to hydraulic disruptions as a result of recycling.

In the proposal, the Agency attempted to identify the subset of systems that would be most susceptible to hydraulic surges by only requiring that systems without equalization or treatment (referred to as "direct recycle") meet the reporting requirements. The Agency further limited the applicability of these requirements (including a one-time requirement to submit a recycle self-assessment) to those direct recycle systems that employ 20 or fewer filters to meet production requirements during a selected month, and recycle spent filter backwash water, thickener supernatant, and/or liquids from dewatering process within the treatment process. The self-assessment required that a monitoring plan, one month of hydraulic flow monitoring, and a self-assessment report containing additional recycle information be submitted to the State. After reviewing the self-assessment, the State would have been required to make a determination whether to require modifications to a system's recycle practice in order to protect public health and report the determination to EPA. The self-assessment was designed to provide the State with adequate information to make this determination.

3. What Major Comments Were Received?

The Agency received many comments on the Direct Recycle Reporting in the proposed rule. The proposed rule only applied to conventional filtration plants which did not practice equalization or treatment of recycle and which utilized fewer than 20 filters to meet demand. Many commenters believed that the operational values used in the analysis conducted by the Agency to arrive at a 20 filter cut-off did not accurately represent the true range of values witnessed throughout the country. Similarly, many commenters noted that excluding systems that treat or equalize recycle flows was inappropriate because of the lack of clearly defined, widely-used parameters for the definitions of equalization and treatment of recycle.

The Agency also received significant comment on the proposed hydraulic flow monitoring associated with this requirement. Many commenters disagreed with the appropriateness of hydraulic flow monitoring, citing a range of problems with the process including the amount of data which would be collected, determining the month in which monitoring should take place, and the time of day monitoring should take place. States noted that submittal of self-assessment reports and requirement for a State determination would result in an increased burden, and, that given resource limitations, could be problematic.

4. What Was the Basis for Revising the Proposal?

After evaluating the information submitted by commenters, EPA believes that the goal of this requirement can be achieved more efficiently by slightly modifying this requirement. Rather than requiring only certain conventional filtration systems to develop, obtain State approval of, and implement a hydraulic flow monitoring program, the Agency believes that all conventional filtration systems that practice recycle can assemble existing information on recycle flow volumes, treatment/equalization and other parameters that is adequate for States to evaluate whether recycle modifications are necessary. Some of the information would be reported by all affected systems to the State, which will facilitate State identification of those systems where recycle practices warrant closer scrutiny. Additional information would be maintained on-site by the system and available to the State for review.

Today's final rule now applies to all conventional filtration systems that recycle. In requiring only those systems that did not provide treatment or equalization of their recycle streams and which utilized less than 20 filters to comply with the proposed requirement, the Agency was attempting to identify the subset of systems where hydraulic surge was a particular risk. Given the wide variability among system operations as noted by commenters, the Agency believes it to be more protective of public health to require all conventional filtration systems to comply.

The Agency has also modified flow monitoring and the self-assessment portions of the requirement in the proposal. EPA established hydraulic flow monitoring as a means for developing information to evaluate whether hydraulic surge may cause a plant to exceed its operating capacity

and threaten treatment performance. The self-assessment was intended to serve as a vehicle for providing this information and additional recycle data to the State. The comments highlighted the technical concerns and burden associated with having systems conduct the flow monitoring, develop the self-assessment, and duplicate existing information submitted to the State. EPA believes this same goal can be achieved more efficiently with a modified approach. Today's final rule requires systems to notify the State that they practice recycle, and include, along with a schematic of the system's recycle process, four key pieces of information (typical recycle flow (gpm), highest observed plant flow experienced in the previous year (gpm), design flow for the treatment plant (gpm), and the State-approved operating capacity for the plant where the State has made such determinations). This information will be submitted to the State, so States may evaluate whether recycle practices have the potential to cause a hydraulic surge that may cause a plant to exceed its operating capacity. Systems will not be required to perform flow monitoring, but will still be required to collect certain additional recycle data (as described previously) and keep it on file for State review during sanitary surveys, other inspections (e.g., comprehensive performance evaluations (CPEs)), or other State activities, rather than submit it in a special report to the State. An ancillary benefit of this modification is significantly reduced burden for systems and States because of the removal of the monitoring, associated monitoring plan, and State approval provisions.

C. What Reporting Does the FBRR Require of Direct Filtration Systems That Recycle?

1. What Does Today's Rule Require?

The Agency's goal is to address risks associated with recycle practices in the least burdensome, most effective, and simplest means possible. Accordingly, today's final rule requires that systems that practice direct filtration and recycle spent filter backwash, sludge thickener supernatant, or liquids from dewatering processes, notify the State in writing that they practice recycle. When notifying the State, systems must also provide the following information:

- A plant schematic showing the origin of all recycle flows, the hydraulic conveyance used to transport them, and the location where they are recycled back into the plant; and
- Typical recycle flow (gpm), highest observed plant flow experienced in

the previous year (gpm), design flow for the treatment plant (gpm), and the State-approved operating capacity for the plant where the State has made such determinations.

Additionally, systems must collect and maintain the following information for review by the State, which may, after evaluating the information, require a system to modify their recycle location or recycle practices:

- (1) Copy of the recycle notification and information submitted to the State;
- (2) List of all recycle flows and the frequency with which they are returned;
- (3) Average and maximum backwash flow rate through the filters and the average and maximum duration of the filter backwash process in minutes;
- (4) Typical filter run length and a written summary of how filter run length is determined (headloss, turbidity, time etc.);

(5) The type of treatment provided for the recycle flow; and

(6) Data on the physical dimensions of the equalization and/or treatment units, typical and maximum hydraulic loading rates, type of treatment chemicals used and average dose and frequency of use, and frequency at which solids are removed from treatment units where such units are used.

These requirements are identical to the requirements for conventional filtration systems that recycle, as described in Section III.B. They are discussed in separate preamble sections because in the proposed rule, separate and distinct requirements for the two types of systems were proposed.

2. What Was the Rationale and Basis for the Proposed Requirement?

The Agency proposed that all direct filtration systems that recycle submit a report to the State that would include information on recycle practices. The State would then be required to make a determination of whether modifications to a system's recycle practice would be required.

This component was designed to assist States in addressing the potential negative impact of hydraulic surge and inadequate treatment on direct filtration treatment performance. The first component of today's final rule requires that recycle flows be returned to an appropriate place in the treatment system to ensure that they are given adequate treatment and achieve 2-log removal of *Cryptosporidium*. However, the practice of recycle can still upset treatment performance if not performed properly. Consequently, the Agency developed the direct filtration system requirements to address the following two concerns.

First, as discussed with respect to conventional filtration systems that recycle, during the short duration of a filter backwash recycle event (typically about 15 minutes long), a large volume of water may surge through the treatment plant. This surge can potentially overload treatment capability by challenging the ability of each step within a system (e.g., surges that cause hydraulic flow to exceed design or operating capacity). Reduced filter efficiency can lead to *Cryptosporidium* oocysts passing through to the finished water.

Second, treatment of recycle streams is of utmost importance for direct filtration systems. By definition, direct filtration does not have a sedimentation or solids removal step in the primary treatment train. Any solids which enter the process either are deposited on the filter or travel through the filter. If the recycle flow is not adequately treated before being returned to the primary treatment train, significant numbers of the oocysts captured on a filter during a filter run will be returned to the plant. These oocysts are again loaded onto the filters, increasing the risk that disinfectant-resistant pathogens such as *Cryptosporidium* can slip through filtration, thereby posing a public health risk.

Given the variety and site-specific nature of recycle practices throughout the country, the Agency believed it necessary to require direct filtration systems to notify States that they practice recycle, and provide information the State could utilize to evaluate whether a treatment plant may be susceptible to hydraulic disruptions as a result of recycling, and whether the existing recycle practices sufficiently address potential health risks. This information would allow States to focus resources and prioritize systems where recycle may be a concern.

3. What Major Comments Were Received?

Many States commented that information required to be submitted as part of the proposed Direct Filtration Reporting was in many cases duplicative of information already available to the State. States also noted that submittal of direct filtration reports would result in an increased burden, and that given resource limitations this could be problematic.

Additionally, several commenters, including the EPA's Science Advisory Board, noted that it would be unlikely for a direct filtration system to continue operations and recycle without employing a solids removal step in the recycle train. EPA agrees that this would

be true for systems that recycle on a more or less continuous basis. EPA based assumptions on data from an AWWA Fax Survey (AWWA, 1998) which indicated that eight percent of direct filtration systems that recycled used equalization but not treatment. EPA believes that the Direct Filtration Reporting requirement of today's final rule will allow systems and States to evaluate recycle practices and determine whether existing recycle practices sufficiently address potential health risks.

4. What Was the Basis for Refining the Proposal?

After evaluating the information submitted by commenters, EPA believes that the goal of this requirement can be achieved more efficiently by slightly modifying this requirement. Rather than requiring direct filtration systems to prepare and submit a report on the adequacy of recycle flow treatment, the Agency believes that these systems can notify the State that they recycle and submit some basic flow information. The direct filtration systems would assemble and maintain on-site additional information on recycle flow volumes and treatment/equalization and other parameters that is adequate for States to determine if recycle modifications are necessary.

The final rule requires systems to notify the State that they practice recycle, and include, along with a schematic of the systems recycle process, four key pieces of information (typical recycle flow (gpm), highest observed plant flow experienced in the previous year (gpm), design flow for the treatment plant (gpm), and if applicable the State-approved operating capacity for the plant). This information will be submitted to the State, so States may evaluate whether recycle practices have the potential to cause a hydraulic surge that may cause a plant to exceed its operating capacity. Systems would still be required to collect certain additional recycle data (as described previously) and keep it on file for State review during sanitary surveys, other inspections (e.g., CPEs), or other State activities rather than submit it in a special report to the State. An ancillary benefit of this modification is significantly reduced burden for systems and States.

D. What Is the Compliance Schedule for the FBRR?

1. What Does Today's Rule Require?

Section 1412(b)(10) of SDWA provides that systems must comply with new drinking water rules 36 months

after promulgation unless the Administrator determines that an earlier time is practicable. The Administrator or an authorized State may extend the compliance date by an additional 24 months if capital improvements are necessary.

The Agency developed the requirements of today's final FBRR to provide flexibility for States and systems to implement and comply with the rule. Today's final rule requires that systems must recycle spent filter backwash water, thickener supernatant, or liquids from dewatering processes through the processes of a system's existing conventional or direct filtration system as defined in § 141.2 or an alternate recycle location approved by the State no later than June 8, 2004. Systems that need to make capital improvements to modify their recycle location must complete activities by June 8, 2006. The Agency believes that granting an additional 24 months to the compliance date is appropriate under 1412(b)(10). The Agency estimates that as many as 400 systems are expected to make changes to their recycle location and will require additional time to secure financing for their capital improvements. These improvements may include preliminary planning activities, development of alternatives, selection of consultants and contractors, receipt of State approval and/or permits, and finally installation of new piping, pumps, processes, and instrumentation.

The reporting requirements of today's final rule must be completed no later than December 8, 2003. The schedule for submitting the reporting contained in today's final rule was slightly modified from the proposal to maintain a consistent order of activities and to ensure that systems submit basic recycle information to the State prior to the compliance date for the recycle return location requirement. These reporting requirements were established pursuant to the authority of Section 1445 of SDWA to ensure that States have the appropriate information from systems to determine compliance with the recycle return location requirement of today's final rule.

2. What Major Comments Were Received?

As discussed in the previous sections, the Agency received significant comment on all three proposed provisions. Today's final rule includes some modifications of the proposed provisions, and the compliance schedule has been adjusted accordingly. One argument made by several commenters was that EPA should not require systems or States to undertake

activities before three years from the date a rule is promulgated because it would result in "early implementation" of the rule. EPA notes that the recycle return location requirement of today's final rule does not require compliance until June 8, 2004, three years after promulgation of the rule in the **Federal Register** as required by Section 1412(b)(10) of SDWA. Only minimal reporting is required, pursuant to the authority of Section 1445 of SDWA, at two and a half years after promulgation of today's final rule.

Several commenters indicated that guidance documents would play an important role in implementing and understanding the requirements of the FBRR. In addition to an implementation guidance manual, the Agency is currently developing additional guidance to aid systems and States in complying with the FBRR. EPA intends to solicit input from a variety of stakeholders during the development of the guidance documents, and will ensure that the documents undergo significant technical review by industry experts.

E. What Public Notification and Consumer Confidence Report Requirements Are Contained in the FBRR?

Today's final rule modifies the Public Notification (PN) requirements found in Appendix A and B of subpart Q of Part 141 to include two public notification requirements associated with the FBRR. Today's final rule establishes public notification of a Tier 2 treatment technique violation for failure to comply with the requirements of § 141.76(c) of today's final rule. Additionally, the FBRR establishes public notification of a Tier 3 monitoring and testing violation for failure to notify the State and include the appropriate information collected as part of § 141.76(b) or failure to collect and maintain recycle information as part of § 141.76(d).

Today's rule does not specifically modify the Consumer Confidence Report (CCR) Requirements found in subpart O of part 141. However, consumer confidence reports must contain any violations of treatment techniques or requirements of NPDWRs as specified in § 141.153(d)(6) and § 141.153(f). This includes any such violations of the FBRR.

Updated CCR and PN appendices can be found on the Agency's website at <http://www.epa.gov/safewater/tables.html>.

IV. State Implementation

A. What Special State Primacy Requirements Does the FBRR Contain?

Today's final rule contains one special primacy requirement that a State must meet in order to receive primacy for the rule. A State's application must contain a description of the proper rules or other authority possessed by the State to use Sanitary Surveys, comprehensive performance evaluations (CPEs), other inspections or other activities to evaluate recycle data maintained by systems, and require modifications to recycle practices as necessary. The Agency recognizes that there are numerous mechanisms a State could use to evaluate recycle practices including Sanitary Surveys, CPEs, and other inspection. However, a State must also have the authority to require systems to modify recycle practices after an evaluation has been completed. The proposed rule contained two additional special primacy requirements, which related to approval of recycle locations other than prior to the point of primary coagulant addition and to recycle self-assessments. However, both of these special primacy requirements were related to recycle provisions that have been modified as a result of comments on the proposal. Resultant changes to the recycle provisions have obviated the need for these two special primacy requirements, since recycle is no longer required to be returned prior to the point of primary coagulant addition and recycle self-assessments have been removed from the final rule.

B. What State Information Collection, Recordkeeping and Reporting Requirements Does the FBRR Contain?

Today's final rule includes no specific State information collection, reporting, or recordkeeping requirements. The proposal included State reporting requirements; however changes to the final FBRR provisions (as a result of comments on the proposed rule) have obviated the need for the State self-assessment determination and direct filtration determination reports since these requirements are no longer contained in the final rule. Furthermore, the Agency decided to remove the State reporting requirement associated with the recycle return location as a result of comments on the proposed rule. However, today's rule modifies § 142.14 to require States to keep on file system-specific decisions made under § 141.76 such as approval of alternate recycle locations.

C. How Must a State Obtain Interim Primacy for the FBRR?

To maintain primacy for the Public Water Supply Supervision (PWSS) program and to be eligible for interim primacy enforcement authority for future regulations, States must adopt today's final rule. A State must submit a request for approval of program revisions that adopt the revised MCL or treatment technique and implement regulations within two years of promulgation, unless EPA approves an extension per § 142.12(b). Interim primacy enforcement authority allows States to implement and enforce drinking water regulations once State regulations are effective and the State has submitted a complete and final primacy revision application. To obtain interim primacy, a State must have primacy with respect to each existing NPDWR. Under interim primacy enforcement authority, States are effectively considered to have primacy during the period that EPA is reviewing their primacy revision application.

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

This section summarizes the Health Risk Reduction and Cost Analysis in support of the FBRR as required by section 1412(b)(3)(C) of the 1996 SDWA. In addition, under Executive Order 12866, Regulatory Planning and Review, EPA must estimate the costs and benefits of the FBRR. EPA has prepared an estimate of the costs and benefits to comply with the requirements of this Executive Order and the SDWA Health Risk Reduction and Cost Analysis (USEPA, 2001). This final analysis will be published on the Agency's web site, at <http://www.epa.gov/safewater>. It can also be found in the docket for this rulemaking.

EPA has estimated the total annualized cost for implementing the FBRR and analyzed the total benefits that result from the rule. Total annual costs for the rule are estimated at either \$5.84 million or \$7.2 million in 2000 dollars, depending on whether a three percent or a seven percent discount rate is used to annualize capital and start-up costs. The cost estimate includes capital costs for treatment changes and start-up and annual labor costs for reporting activities. More details, including the basis for these estimates and alternate cost estimates using different cost of capital assumptions are described later in this section. The benefits associated with the FBRR are discussed qualitatively, but remain unquantified because of data limitations.

A. What Are the Costs of the FBRR?

In estimating the costs of today's final rule, the Agency considered impacts on public water systems and on States (including territories and EPA implementation in non-primacy States) and Tribes. The FBRR will result in increased costs to public water systems for reading and understanding the rule, reporting recycle practices to the State, and capital improvements to recycle return locations at up to 400 systems. States will also face implementation costs associated with reading and understanding the rule, obtaining primacy, and evaluating system's recycle reports and recycle practices. The recycle provisions apply to all surface water and GWUDI systems that recycle filter backwash, thickener supernatant, or liquids from dewatering. EPA estimates that the annualized cost of today's final rule will be \$5.84 million or \$7.2 million (annualized using a three percent or seven percent discount rate respectively). Total capital and associated O&M costs associated with modifications to recycle locations at an estimated 371 systems are \$45.2 million, and represent \$5.5 million or \$6.8 million annually (annualized over 20 years using a three percent or seven percent discount rate, respectively). The recycle return provision of today's final rule accounts for 95 percent of total annualized costs. Public Water System expenditures for all provisions are greater than 99 percent (\$5.8 million at a three percent discount rate or \$6.7 million at a seven percent discount rate) of total annualized costs; State expenditures make up less than 1 percent (\$0.07 million at a three percent discount rate or \$0.098 million at a seven percent discount rate). The national estimate of annual system costs for the recycle provisions is based on estimates of system-level costs for the rule and estimates of the number of systems expected to incur each type of cost.

Although EPA has evaluated the cost to drinking water systems and States of all provisions of the rule, there are some costs that the Agency was not able to quantify such as indirect costs to systems. These costs may result if States require systems to make additional changes to their recycle practice based on the data collected under this rule. Additionally, there are uncertainties surrounding rule assumptions that may affect the quantified cost estimates. For example, EPA estimated the number of systems that may be affected by this rule based on survey information. If the surveys underestimated the numbers of systems required to change the return

location of their filter backwash, then the cost of this requirement would be underestimated. However, it is also possible that the surveys overestimated the number of systems required to make changes and this would result in an overestimation of rule costs.

B. What Are the Household Costs of the FBRR?

The mean annual cost per household is \$0.19 and the total annual cost per household is less than \$1.70 for 99 percent of the 31.4 million households potentially affected by today's final rule. The remaining one percent of households will experience a range of costs between \$1.70 and approximately \$100 per year. Only 321 of the 31.4 million households potentially affected by the FBRR (.00001 percent) are expected to incur costs of approximately \$100 per year.

C. What Are the Benefits of the FBRR?

The primary benefits of today's final rule come from reductions in the risk of illness from microbial pathogens in drinking water. In particular, FBRR focuses on reducing the risk associated with disinfection resistant pathogens, such as *Cryptosporidium*.

Available literature research demonstrates that increased hydraulic loading or disruptive hydraulic currents, such as may be experienced when plants exceed State-approved operating capacity or when recycle is returned directly into the sedimentation basin, can disrupt filter (Cleasby, 1963; Glasgow and Wheatley, 1998; McTigue *et al.*, 1998) and sedimentation (Fulton, 1987; Logsdon, 1987; Cleasby, 1990) performance. However, the literature does not quantify the extent to which performance can be lowered and, more specifically, does not quantify the decrease in *Cryptosporidium* removal that may be experienced during direct recycle events. Specifically, there is a lack of treatment performance data to accurately model the oocysts removal achieved by individual full-scale treatment processes and the impact recycle may have on treatment unit *Cryptosporidium* removal and resulting finished water quality. However, as indicated previously, some studies have shown that when recycle is performed in accordance with the requirements of the FBRR, *Cryptosporidium* removal is not impaired.

The goal of the FBRR is to reduce the potential for oocysts getting into the finished water and causing cases of cryptosporidiosis. Other disinfection-resistant pathogens may also be removed more efficiently due to implementation of these provisions.

Exposure to other pathogenic protozoa, such as *Giardia*, or other emerging microbial pathogens is likely to be reduced by the this rule as well.

In addition to preventing illnesses, this rule is expected to have other non-health related benefits. These benefits result from avoiding non-health related costs associated with waterborne disease outbreaks. During an outbreak, local governments and water systems must issue warnings and alerts and may need to provide an alternative source of water. Systems also face negative publicity and possibly legal costs. Businesses have to supply their customers and employees with alternative sources of water and some, especially restaurants, may even have to temporarily close. Households also have to either boil their water, purchase water, or obtain water from another source. The monetary costs associated with an outbreak can be difficult to quantify and will vary with respect to a host of criteria. However, one study of a *Giardia* outbreak in Luzerne County, Pennsylvania estimated these non-health related outbreak costs to be quite significant (Harrington *et al.*, 1985). This study estimated losses to individuals due to actions taken to avoid the contaminated water at between \$19 million and \$49 million, in 1984 dollars. (\$31M-\$81M in 2000\$). Losses due to averting actions for restaurants and bars totaled \$1 million and \$0.6 million for schools and other businesses, in 1984 dollars. The burden for government agencies was \$230,000 and the outbreak cost the water utility an estimated \$1.8 million, again in 1984 dollars.

D. What Are the Incremental Costs and Benefits of the FBRR?

Analytical limitation in the estimation of monetized benefits for the FBRR prevented the Agency from quantitatively describing the incremental benefit of the various regulatory alternatives considered for this rulemaking. The RIA supporting the final FBRR provides detailed information on the incremental costs of various rule components.

E. Are There Benefits From the Reduction of Co-Occurring Contaminants?

Improvements in recycle practices may also reduce exposure to *Giardia lamblia* and emerging disinfection resistant pathogens, such as microsporidia, *Toxoplasma*, and *Cyclospora*. The frequency and extent that FBRR would reduce risk from these other contaminants has not been quantitatively evaluated because the

Agency lacked removal efficiency data for these various technologies as well as co-occurrence data.

F. Is There Increased Risk From Other Contaminants?

The Agency has not identified any increased risk from other contaminants as a result of promulgating the FBRR.

G. What Are the Uncertainties in Risk, Benefit and Cost Estimates for the FBRR?

EPA has included a detailed discussion of the possible sources of uncertainty in risk, benefit and cost estimates in the cost-benefit analysis. As noted earlier, the risk and benefits have been expressed qualitatively for this rule, and associated sources of uncertainty include occurrence of *Cryptosporidium* oocysts in source waters and finished waters, reduction of *Cryptosporidium* oocysts due to improved treatment, viability and infectivity of *Cryptosporidium* oocysts, and the characterization of risk. Uncertainty associated with costs include assumptions with respect to changes a system might make to their point of recycle, assumptions about costs of labor, maintenance, and capital, and the number of systems expected to undertake certain activities. The Agency believes that the qualitative risks and benefits, and the quantitative costs have been accurately portrayed. Discussions and analysis of risks, benefits, and costs indicate where uncertainty may be introduced and to the extent possible, the effect uncertainty may have on analysis (EPA, 2001).

H. What Is the Benefit/Cost Determination for the FBRR?

The Agency has determined that the benefits of the FBRR justify their cost on a qualitative basis. The FBRR will reduce the potential for improper recycle practices to upset treatment plant performance during recycle events. Today's rule will therefore help prevent *Cryptosporidium* oocysts and other contaminants from entering finished drinking water supplies and causing endemic illness or costly waterborne disease outbreaks.

The Agency strongly believes that returning *Cryptosporidium* to the treatment process in recycle flows, if performed improperly, can create additional public health risk. Therefore, the Agency is requiring that recycle flows be returned to the point such that all steps of a system's conventional or direct filtration will be employed to ensure that the system continues to achieve at least a 2-log removal of *Cryptosporidium*. As indicated

previously, some studies have shown that when recycle is performed in accordance with the requirements of the FBRR, *Cryptosporidium* removal is not impaired. Additionally, today's rule also will aid States and systems by ensuring that they have the requisite information to evaluate whether a treatment plant may be susceptible to hydraulic disruptions as a result of recycling, and whether the existing recycle practices sufficiently addresses potential health risks.

VI. Other Requirements

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

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

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

For purposes of assessing the impacts of today's rule on small entities, EPA considered small entities to be PWSs serving fewer than 10,000 persons. This is the cut-off level specified by Congress in the 1996 Amendments to the Safe Drinking Water Act for small system flexibility provisions. In accordance with the RFA requirements, EPA proposed using this alternative definition in the **Federal Register** (63 FR 7620, February 13, 1998), requested comment, consulted with the Small Business Administration (SBA), and expressed its intention to use the alternative definition for all future drinking water regulations in the Consumer Confidence Reports regulation (63 FR 44511, August 19, 1998). EPA has thus used this alternative definition in this final rule.

After considering the economic impacts of today's final rule on small entities, I certify that this action will not

have a significant economic impact on a substantial number of small entities.

In accordance with section 603 of the RFA, EPA prepared an initial regulatory flexibility analysis (IRFA) for the proposed rule (see 65 FR 19046, 19126-27), and convened a Small Business Advocacy Review (SBAR) Panel to obtain advice and recommendations from representatives of small entities that would potentially be regulated by the rule in accordance with section 609(b) of the RFA. A detailed discussion of the Panel's advice and recommendations is found in the Panel Report found in the docket for today's final rule (EPA, 1998k). A summary of the Panel's recommendations is presented in the proposal (65 FR 19046, 19127-19130).

EPA originally developed an IRFA and convened an SBAR Panel because one of the preliminary alternatives being evaluated by the Agency was a ban on the recycle of spent filter backwash. This preliminary alternative would have resulted in substantial costs to all conventional and direct filtration systems that practiced recycle including small entities. After development of the IRFA and completion of the SBAR Panel, the Agency determined that a ban on recycle was not an appropriate alternative and removed it from consideration. The Agency re-evaluated the economic effects on small entities after publication of the April 10, 2000 FBRR proposal and was able to certify that today's final rule will not have a significant economic impact on a substantial number of small entities.

Of the 3,840 small entities potentially affected by the FBRR, 93 percent are expected to incur average annualized costs of less than \$50. This equates to approximately 0.001 percent of average annual revenue. The remaining 7 percent (278 systems) are expected to incur average annualized costs of approximately \$2,200, or 0.08 percent of average annual revenue. The Agency has included a detailed description of this analysis in the Regulatory Flexibility Screening Analysis prepared for the final rule (USEPA, 2000f).

B. Paperwork Reduction Act

The Office of Management and Budget has approved the information collection requirements contained in this rule under the provisions of the Paperwork Reduction Act, 44 U.S.C. 3501 et seq. and has assigned OMB control number 2040-0224. The information collected as a result of this rule will allow the States to determine appropriate requirements for specific systems, in some cases, and to evaluate compliance with the rule. For the first three years

after the effective date of the FBRR, the major information requirements are the required notification to States by systems that recycle, including a plant schematic and flow information that must accompany the notification. The information collection requirements in section 141.76, for systems, and section 142.14, for States, are mandatory. The information collected is not confidential.

The preliminary estimate of aggregate annual average burden hours for the first three years after the effective date of the FBRR is 66,363. For systems these hours consist of reading and understanding the rule, mobilization and planning, and preparation of the State notifications. For States these hours consist of reading and understanding the rule, obtaining primacy, mobilization and planning, and staff training. The annual average aggregate cost estimate over the first three years is \$0 for capital, and \$0 for operation and maintenance. The burden hours per response annually is 8.4 hours. The frequency of response (average responses per respondent) is 4.0 annually. The estimated number of likely respondents is 1,986 (the product of burden hours per response, frequency, and respondents does not total the annual average burden hours due to rounding).

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

An Agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number. The OMB control numbers for EPA's regulations are listed in 40 CFR part 9 and 48 CFR chapter 15. The OMB control number(s) for the information collection requirements in this rule will be listed in an amendment to 40 CFR part 9 in a subsequent **Federal Register** document after OMB approves the ICR.

C. Unfunded Mandates Reform Act of 1995

Title II of the Unfunded Mandates Reform Act of 1995 (UMRA), Public Law 104-4, establishes requirements for Federal agencies to assess the effects of their regulatory actions on State, local, and Tribal governments and the private sector. Under UMRA section 202, EPA generally must prepare a written statement, including a cost-benefit analysis, for proposed and final rules with "Federal mandates" that may result in expenditures by State, local, and Tribal governments, in the aggregate, or to the private sector, of \$100 million or more in any one year. Before promulgating an EPA rule, for which a written statement is needed, section 205 of the UMRA generally requires EPA to identify and consider a reasonable number of regulatory alternatives and adopt the least costly, most cost-effective or least burdensome alternative that achieves the objectives of the rule. The provisions of section 205 do not apply when they are inconsistent with applicable law. Moreover, section 205 allows EPA to adopt an alternative other than the least costly, most cost effective or least burdensome alternative if the Administrator publishes with the final rule an explanation why that alternative was not adopted.

Before EPA establishes any regulatory requirements that may significantly or uniquely affect small governments, including Tribal governments, it must have developed, under section 203 of the UMRA, a small government agency plan. The plan must provide for notifying potentially affected small governments, enabling officials of affected small governments to have meaningful and timely input in the development of EPA regulatory proposals with significant Federal intergovernmental mandates and informing, educating, and advising small governments on compliance with the regulatory requirements.

EPA has determined that this rule does not contain a Federal mandate that may result in expenditures of \$100 million or more for the State, local and Tribal governments, in the aggregate, or the private sector in any one year. The estimated annual cost of this rule is \$5.84 million at a three percent discount or and \$7.2 million at a seven percent discount rate. Thus today's rule is not subject to the requirements of sections 202 and 205 of the UMRA.

EPA has determined that this rule contains no regulatory requirements that might significantly or uniquely affect small governments. Of the 1,574 small

government entities potentially affected by the FBRR, 93 percent are expected to incur average annualized costs of less than \$50 dollars. This equates to approximately 0.002 percent of average annual revenue. The remaining 7 percent (114 systems) are only expected to incur average annualized costs of approximately \$2,200 dollars or 0.09 percent of average annual revenue. Thus, today's rule is not subject to the requirements of section 203 of UMRA.

Nevertheless, EPA has tried to ensure that State, local, and Tribal governments had opportunities to provide comment. EPA consulted with small governments to address impacts of regulatory requirements in the rule that might significantly or uniquely affect small governments. As discussed next, a variety of stakeholders, including small governments, were provided the opportunity for timely and meaningful participation in the regulatory development process. EPA used these opportunities to notify potentially affected small governments of regulatory requirements being considered.

EPA began outreach efforts to develop the FBRR in the summer of 1998. Two public stakeholder meetings, which were announced in the **Federal Register**, were held on July 22-23, 1998, in Lakewood, Colorado, and on March 3-4, 1999, in Dallas, Texas. Stakeholders include representatives of State, local and Tribal governments, environmental groups and public and private public water systems. In addition to these meetings, EPA has held several formal and informal meetings with stakeholders including the Association of State Drinking Water Administrators. A summary of each meeting and attendees is available in the public docket for this rule. EPA also convened a Small Business Advocacy Review (SBAR) Panel in accordance with the Regulatory Flexibility Act (RFA), as amended by the Small Business Regulatory Enforcement Fairness Act (SBREFA) to address small entity concerns including those of small local governments. The SBAR Panel allows small regulated entities to provide input to EPA early in the regulatory development process. In early June 1999, EPA mailed an informal draft of the FBRR preamble to the approximately 100 stakeholders who attended one of the public stakeholder meetings. Members of trade associations and the SBREFA Panel also received the draft preamble. EPA received valuable suggestions and stakeholder input from 15 State representatives, trade associations, environmental interest groups, and individual stakeholders. The majority of concerns dealt with

reducing burden on small systems and maintaining flexibility.

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

At the OGWDW/Inter Tribal Council of Arizona meeting, representatives from 15 Tribes participated. The presentation materials and meeting summary were sent to over 500 Tribes and tribal organizations. Additionally, EPA contacted each of the 12 Native American Drinking Water State Revolving Fund Advisors to invite them, and representatives of their organizations to the stakeholder meetings described previously.

During the comment period for today's final rule, the Agency held a public meeting in Washington DC on April 14, 2000 (EPA,2000d). Additionally, the proposed rule was either presented or discussed in nearly 50 meetings across the US. Finally, EPA mailed approximately 200 copies of the proposed rule to stakeholders requesting comment. EPA received 67 comments from a variety of stakeholders including 24 States, 21 municipalities, one Tribe, one elected official, two consultants, eight trade groups, and four private industries.

In addition, EPA will educate, inform, and advise small systems, including those run by small governments, about the FBRR requirements. The Agency is developing plain-English guidance that will explain what actions a small entity must take to comply with the rule. Also, the Agency has developed fact sheets that concisely describe various aspects and requirements of the FBRR. These fact sheets are available by calling the Safe Drinking Water Hotline at 800-426-4791.

D. National Technology Transfer and Advancement Act

As noted in the proposed rule, section 12(d) of the National Technology Transfer and Advancement Act of 1995

(NTAA), Public Law No. 104-113, Section 12(d) (15 U.S.C. 272), directs EPA to use voluntary consensus standards in its regulatory activities unless to do so would be inconsistent with applicable law or otherwise impractical. Voluntary consensus standards are technical standards (e.g., materials specifications, test methods, sampling procedures, and business practices) that are developed or adopted by voluntary consensus standards bodies. The NTAA directs EPA to provide Congress, through the Office of Management and Budget, explanations when the Agency decides not to use available and applicable voluntary consensus standards.

This action does not involve technical standards. Therefore, EPA did not consider the use of any voluntary consensus standards. We did not receive any comments identifying potentially-applicable voluntary consensus standards that we should consider using either.

E. Executive Order 12866: Regulatory Planning and Review

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

1. Have an annual effect on the economy of \$100 million or more or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or Tribal governments or communities;
2. Create a serious inconsistency or otherwise interfere with an action taken or planned by another agency;
3. Materially alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients thereof, or;
4. Raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in the Executive Order.

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

F. Executive Order 12898: Environmental Justice

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

On March 12, 1998, the Agency held a stakeholder meeting to address various components of pending drinking water regulations and how they may impact sensitive sub-populations, minority populations, and low-income populations. Topics discussed included treatment techniques, costs and benefits, data quality, health effects, and the regulatory process. Participants included national, State, Tribal, municipal, and individual stakeholders. EPA conducted the meetings by video conference call between 11 cities. This meeting was a continuation of stakeholder meetings that started in 1995 to obtain input on the Agency's drinking water programs. The major objectives for the March 12, 1998 meeting were:

- Solicit ideas from stakeholders on known issues concerning current drinking water regulatory efforts;
- Identify key issues of concern to stakeholders, and;
- Receive suggestions from stakeholders concerning ways to increase representation of communities in EPA regulatory efforts.

In addition, EPA developed a plain-English guide specifically for this meeting to assist stakeholders in understanding the multiple and sometimes complex issues surrounding drinking water regulation.

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

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

the planned rule on children and explain why the planned regulation is preferable to other potentially effective and reasonably feasible alternatives considered by the Agency.

While this final rule is not subject to the Executive Order because it is not economically significant as defined in Executive Order 12866, we nonetheless have reason to believe that the environmental health or safety risk addressed by this action may have a disproportionate effect on children. As a matter of EPA policy, we therefore have assessed the environmental health effects of *Cryptosporidium* on children. The results of this assessment are contained in cost-benefit analysis supporting the FBRR (EPA, 2001). A copy of the analysis and supporting documents is available for public review in the Office of Water docket at 401 M St. SW., Washington, DC.

The risk of illness and death due to cryptosporidiosis depends on several factors, including age, nutrition, exposure, genetic variability, disease and immune status of the individual. Mortality resulting from diarrhea shows the greatest risk of mortality occurring among the very young and elderly (Gerba *et al.*, 1996). For *Cryptosporidium*, young children are a vulnerable population subject to infectious diarrhea (CDC 1994). Cryptosporidiosis is prevalent worldwide, and its occurrence is higher in children than in adults (Fayer and Ungar, 1986).

Cryptosporidiosis appears to be more prevalent in populations such as infants, that may not have established immunity against the disease and may be in greater contact with environmentally contaminated surfaces (DuPont, *et al.*, 1995). An infected child may spread the disease to other children or family members. Evidence of such secondary transmission of cryptosporidiosis from children to household and other close contacts has been found in a number of outbreak investigations (Casemore, 1990; Cordell *et al.*, 1997; Frost *et al.*, 1997). Chapell *et al.*, (1999) found that prior exposure to *Cryptosporidium* through the ingestion of a low oocyst dose provides protection from infection and illness. However, it is not known whether this immunity is life-long or temporary. Data also indicate that either mothers confer short term immunity to their children or that babies have reduced exposure to *Cryptosporidium*, resulting in a decreased incidence of infection during the first year of life. For example, in a survey of over 30,000 stool sample analyses from different patients in the United Kingdom, the 1–5 year age group

suffered a much higher infection rate than individuals less than one year of age. For children under one year of age, those older than six months of age showed a higher rate of infection than individuals aged fewer than six months (Casemore, 1990).

EPA has not been able to quantify the health effects for children as a result of *Cryptosporidium*-contaminated drinking water. However, the result of the FBRR will be a reduction in the risk of illness for the entire population, including children. Because available evidence indicates that children may be more vulnerable to Cryptosporidiosis than the rest of the population, the FBRR would, therefore, result in greater risk reduction for children than for the general population.

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

In accordance with section 1412 (d) and (e) of the SDWA, the Agency discussed or submitted possible FBRR requirements to the Science Advisory Board, National Drinking Water Advisory Council (NDWAC), and to the Secretary of Health and Human Services and requested comment from the Science Advisory Board (SAB) on the FBRR.

On March 13th and 14th, 2000 in Washington, DC, the Agency met with the Science Advisory Board during meetings open to the public where several of the Agency's drinking water rules were discussed. A copy of the SAB's comments are found in the docket (EPA, 2000n).

On May 10th, 2000 in San Francisco, California, the Agency presented the FBRR to NDWAC. A copy of the materials presented to the NDWAC as well as the charge presented to the council are found in the docket (EPA, 2000g). A copy of NDWAC's recommendations are also found in the docket (NDWAC, 2000).

EPA invited the Secretary of Health and Human Services to the April 14th, 2000 informational meeting regarding the proposed Long Term 1 Enhanced Surface Water Treatment and Filter Backwash Rule and consulted with the Center for Disease Control (CDC) during June 20, 2000 and October 10, 2000, conference calls with the Center's Working Group on Waterborne Cryptosporidiosis. The meeting notes for these calls are found in the docket for today's rule (CDC, 2000b). CDC's role as an Agency of the Department of Health and Human Services is to provide a system of health surveillance to monitor and prevent outbreak of

diseases. With the assistance of States and other partners, CDC guards against international disease transmission, maintains national health statistics, provides immunization services and supports research into disease and injury prevention.

Only SAB provided substantive comments on the FBRR. SAB had several recommendations including recommending against requirements that would alter the design of direct recycle systems and recommending against requiring that washwater flows be recycled ahead of the point of coagulant addition. Today's final FBRR is consistent with the recommendations of the SAB.

I. Executive Order 13132: Executive Orders on Federalism

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

This final rule does not have federalism implications. It will not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132. Today's final rule does not have a substantial direct effect on local and State governments because it is not expected to impose substantial direct compliance costs. The rule imposes annualized compliance costs of approximately \$3.78 or \$4.64 million (at 3 percent and 7 percent discount rates, respectively) per year for local and State governments. Only \$0.07 or \$0.98 million (at 3 percent and 7 percent discount rates respectively,) of these costs are attributable to States, while \$0.64 or \$0.82 million (at 3 percent and 7 percent discount rates, respectively) is attributable to approximately 1,575 local governments serving fewer than 10,000 persons and the remaining \$4.7 million or \$5.8 million (at 3 percent and 7 percent discount rates, respectively) is attributable to approximately 980 local governments serving 10,000 or more persons. Furthermore, the rule does not

have a substantial direct effect on the relationship between the national government and the States, or the distribution of power and responsibilities among the various levels of government as specified in Executive Order 13132 because the rule does not change the current roles and relationships of the Federal government, State governments and local governments in implementing drinking water programs. Thus, Executive Order 13132 does not apply to this rule. Although the Executive Order does not apply to this rule, EPA did consult with State and local officials in developing this rule. In addition to our outreach efforts described earlier, on May 30, 2000, the Agency held a meeting in Washington, DC with ten representatives of elected State and local officials to discuss how new Federal drinking water regulations (FBRR, LT1ESWTR, Ground Water Rule, Radon Rule, Radionuclides Rule, and Arsenic Rule) may affect State, county, and local governments. Throughout the consultation, stakeholders asked EPA for clarification of basic concepts and rule elements. EPA addressed these issues throughout the consultation and provided background and clarification to promote better understanding of the issues. For example, stakeholders asked EPA to describe what Cryptosporidium is and how individuals are diagnosed with cryptosporidiosis. A detailed summary of this consultation meeting and the concerns raised is found in the docket (EPA, 2000h). No significant concerns were raised regarding the FBRR.

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

On November 6, 2000, the President issued Executive Order 13175 (65 FR 67249) entitled, "Consultation and Coordination with Indian Tribal Governments." Executive Order 13175 took effect on January 6, 2001, and

revokes Executive Order 13084 (Tribal Consultation) as of that date. EPA developed this final rule, however, during the period when Executive Order 13084 was in effect; thus, EPA addressed Tribal considerations under Executive Order 13084.

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

Today's rule does not significantly or uniquely affect the communities of Indian Tribal governments, nor will it impose substantial direct compliance costs on them. This rule will affect fewer than 22 of the 987 (2 percent) total tribal drinking water systems. Of these 22 systems, 20 are estimated to incur annualized compliance costs of less than \$50 per year or 0.001 percent of average annual revenue. The remaining two systems are estimated to incur annualized compliance costs of approximately \$2,200 per year or 0.08

percent of average annual revenue. Accordingly, the requirements of section 3(b) of Executive Order 13084 do not apply to this rule.

K. Likely Effect of Compliance With the FBRR on the Technical, Financial, and Managerial Capacity of Public Water Systems

Section 1420(d)(3) of the SDWA as amended requires that, in promulgating a NPDWR, the Administrator must include an analysis of the likely effect of compliance with the regulation on the technical, financial, and managerial capacity of public water systems. This analysis can be found in the FBRR cost-benefit analysis (EPA, 2001).

Overall water system capacity is defined in EPA guidance (EPA, 1998j) as the ability to plan for, achieve, and maintain compliance with applicable drinking water standards. Capacity has three components: technical, managerial, and financial.

Technical capacity is the physical and operational ability of a water system to meet SDWA requirements. Technical capacity 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:

Technical Capacity

Source water adequacy	Does the system have a reliable source of drinking water? Is the source of generally good quality and adequately protected?
Infrastructure adequacy	Can the system provide water that meets SDWA standards? What is the condition of its infrastructure, including well(s) or source water intakes, treatment, storage, and distribution? What is the infrastructure's life expectancy? Does the system have a capital improvement plan?
Technical knowledge and implementation	Is the system's operator certified? Does the operator have sufficient technical knowledge of applicable standards? Can the operator effectively implement this technical knowledge? Does the operator understand the system's technical and operational characteristics? Does the system have an effective operation and maintenance program?

Managerial Capacity

Ownership accountability	Are the system owner(s) clearly identified? Can they be held accountable for the system?
Staffing and organization	Are the system operator(s) and manager(s) clearly identified? Is the system properly organized and staffed? Do personnel understand the management aspects of regulatory requirements and system operations? Do they have adequate expertise to manage water system operations? Do personnel have the necessary licenses and certifications?
Effective external linkages	Does the system interact well with customers, regulators, and other entities? Is the system aware of available external resources, such as technical and financial assistance?

Financial Capacity

Revenue sufficiency	Do revenues cover costs? Are water rates and charges adequate to cover the cost of water?
Credit worthiness	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?

Generally, systems affected by this rule are not required to make significant modifications to the treatment process to meet FBRR requirements. Therefore, most systems are not expected to experience a significant impact on their technical, financial, or managerial capacity.

L. Plain Language

Executive Order 12866 requires each agency to write its rules in plain language. Readable regulations help the public find requirements quickly and understand them easily. They increase compliance, strengthen enforcement, and decrease mistakes, frustration, phone calls, appeals, and distrust of government. Of the several techniques typically utilized for writing readably, using a question and answer format, and using the word, "you" for whoever must comply, do the most to improve the look and sound of a regulation. The preamble for today's final rule uses the first principle and was developed using a plain language question and answer format. Today's final rule language does not use these principles since the rule only modifies or adds to existing regulatory language that is in the previous regulatory language format. However, EPA has made every effort to write the rule in as clear, concise, and unambiguous manner as possible.

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

Executive Order 13211, "Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use" (66 FR 28355 (May 22, 2001)), provides that agencies shall prepare and submit to the Administrator

of the Office of Information and Regulatory Affairs, Office of Management and Budget, a Statement of Energy Effects for certain actions identified as "significant energy actions." Section 4(b) of Executive Order 13211 defines "significant energy actions" as "any action by an agency (normally published in the **Federal Register**) that promulgates or is expected to lead to the promulgation of a final rule or regulation, including notices of inquiry, advance notices of proposed rulemaking, and notices of proposed rulemaking: (1)(i) That is a significant regulatory action under Executive Order 12866 or any successor order, and (ii) is likely to have a significant adverse effect on the supply, distribution, or use of energy; or (2) that is designated by the Administrator of the Office of Information and Regulatory Affairs as a significant energy action."

We have not prepared a Statement of Energy Effects for this final rule because this rule is not a significant energy action, as defined in Executive Order 13211. While this rule is a significant regulatory action under Executive Order 12866, it is not likely to have a significant adverse effect on the supply, distribution, or use of energy.

N. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate,

the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. A major rule cannot take effect until 60 days after it is published in the **Federal Register**. This action is not a "major rule" as defined by 5 U.S.C. 804(2). This rule will be effective August 7, 2001.

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List of Subjects

40 CFR Part 9

Reporting and recordkeeping requirements.

40 CFR Part 141

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

40 CFR Part 142

Environmental protection, Administrative practice and procedure,

Chemicals, Indians-lands, Reporting and recordkeeping requirements, Water supply.

Dated: May 23, 2001.

Christine Todd Whitman,
Administrator.

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

PART 9—[AMENDED]

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

Authority: 7 U.S.C. 135 *et seq.*, 136-136y; 15 U.S.C. 2001, 2003, 2005, 2006, 2601-2671; 21 U.S.C. 331j, 346a, 348; 31 U.S.C. 9701; 33 U.S.C. 1251 *et seq.*, 1311, 1313d, 1314, 1318, 1321, 1326-1330, 1324, 1344, 1345 (d) and (e), 1361; E.O. 11735, 38 FR 21243, 3 CFR, 1971-1975 Comp. p. 973; 42 U.S.C. 241, 242b, 243, 246, 300f, 300g, 300g-1, 300g-2, 300g-3, 300g-4, 300g-5, 300g-6, 300j-1, 300j-2, 300j-3, 300j-4, 300j-9, 1857 *et seq.*, 6901-992k, 7401-7671q, 7542, 9601-9657, 11023, 11048.

2. In § 9.1 the table is amended by adding under the indicated heading the new entry in numerical order to read as follows:

§ 9.1 OMB Approvals under the Paperwork Reduction Act.

* * * * *	40 CFR citation	OMB control No.
* * * * *	National Primary Drinking Water Regulations	
* * * * *	141.76	2040-0224
* * * * *		*

PART 141—NATIONAL PRIMARY DRINKING WATER REGULATIONS

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

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

4. Subpart H is amended by adding § 141.76 to read as follows:

§ 141.76 Recycle Provisions.

(a) *Applicability.* All subpart H systems that employ conventional filtration or direct filtration treatment and that recycle spent filter backwash water, thickener supernatant, or liquids from dewatering processes must meet the requirements in paragraphs (b) through (d) of this section.

(b) *Reporting.* A system must notify the State in writing by December 8, 2003, if the system recycles spent filter backwash water, thickener supernatant, or liquids from dewatering processes. This notification must include, at a minimum, the information specified in paragraphs (b)(1) and (2) of this section.

(1) A plant schematic showing the origin of all flows which are recycled (including, but not limited to, spent filter backwash water, thickener supernatant, and liquids from dewatering processes), the hydraulic conveyance used to transport them, and the location where they are re-introduced back into the treatment plant.

(2) Typical recycle flow in gallons per minute (gpm), the highest observed plant flow experienced in the previous year (gpm), design flow for the treatment plant (gpm), and State-approved operating capacity for the

plant where the State has made such determinations.

(c) *Treatment technique requirement.* Any system that recycles spent filter backwash water, thickener supernatant, or liquids from dewatering processes must return these flows through the processes of a system's existing conventional or direct filtration system as defined in § 141.2 or at an alternate location approved by the State by June 8, 2004. If capital improvements are required to modify the recycle location to meet this requirement, all capital improvements must be completed no later than June 8, 2006.

(d) *Recordkeeping.* The system must collect and retain on file recycle flow information specified in paragraphs (d)(1) through (6) of this section for review and evaluation by the State beginning June 8, 2004.

(1) Copy of the recycle notification and information submitted to the State under paragraph (b) of this section.

(2) List of all recycle flows and the frequency with which they are returned.

(3) Average and maximum backwash flow rate through the filters and the average and maximum duration of the filter backwash process in minutes.

(4) Typical filter run length and a written summary of how filter run length is determined.

(5) The type of treatment provided for the recycle flow.

(6) Data on the physical dimensions of the equalization and/or treatment units, typical and maximum hydraulic loading rates, type of treatment chemicals used and average dose and frequency of use, and frequency at which solids are removed, if applicable.

5. Appendix A to Subpart Q of Part 141 is amended by adding a new entry "8." in numerical order under I.A. to read as follows:

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

Contaminant	MCL/MRDL/TT violations ²		Monitoring and testing procedure violations	
	Tier of public notice required	Citation	Tier of public notice required	Citation
1. Violations of National Primary Drinking Water Regulations (NPDWR): ³				
A. Microbiological Contaminants				
* * * * *				
8. Filter Backwash Recycling Rule violations	2	141.76	3	141.76
* * * * *				

Appendix A—Endnotes

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

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

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.

* * * * *

6. Appendix B to Subpart Q of Part 141 is amended by revising B and entry "7." under B. to read as follows:

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

Contaminant	MCLG ¹ mg/L	MCL ² mg/L	Standard health effects language for public notification
National Primary Drinking Water Regulations (NPDWR):			
* * * * *			
B. Surface Water Treatment Rule (SWTR), Interim Enhanced Surface Water Treatment Rule (IESWTR) and Filter Backwash Recycling Rule (FBRR) violations:			
* * * * *			
7. Cryptosporidium (IESWTR/FBRR).			
* * * * *			

Appendix B—Endnotes

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

* * * * *

PART 142—NATIONAL PRIMARY DRINKING WATER REGULATIONS IMPLEMENTATION

7. 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.

8. Section 142.14 is amended by removing the word “and” at the end of the paragraph (a)(4)(ii)(A)(7) and revising paragraph (a)(4)(ii)(A)(8) and adding paragraph (a)(4)(ii)(A)(9) to read as follows:

§ 142.14 Records kept by States.

- (a) * * *
- (4) * * *
- (ii) * * *

(A) * * *

(8) Section 141.75(b)(2)(iv)—Any decision to allow reduced reporting by a filtered public water system; and

(9) Section 141.76—Any decisions made to approve alternate recycle locations, require modifications to recycle return locations, or require modifications to recycle practices.

* * * * *

9. Section 142.16 is amended by adding paragraph (i) to read as follows:

§ 142.16 Special primacy requirements.

* * * * *

(i) *Requirements for States to adopt 40 CFR part 141, § 141.76 Recycle Provisions.* In addition to the general primacy requirements enumerated elsewhere in this part, including the requirement that the State provisions

are no less stringent than the federal requirements, an application for approval of a State program revision that adopts 40 CFR part 141, § 141.76 Recycle Provisions must contain the information specified in this paragraph: (1) State practices or procedures. (i) Section 141.76(d) of this chapter—States must have the proper rules and authority to use Sanitary Surveys, comprehensive performance evaluations (CPEs), other inspections, or other activities to evaluate recycle data maintained by systems under § 141.76(d) of this chapter and require modifications to recycle practices.

(ii) [Reserved]

(2) [Reserved]

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