EXHIBIT 12

(B) The report covering the period covering April 1 to June 30 shall be submitted by the following August 31.

(C) The report for the period from July 1 to September 30 shall be submitted by the following November 30.

(D) The report for the quarterly compliance period from October 1 to December 31 shall be submitted by the following February 28.

(vi) The report for the quarterly compliance period from April 1, 2010 to May 31, 2010 shall be submitted by August 31, 2010.

(vii) The report for the last quarterly compliance period from June 1, 2010 to September 30, 2010 shall be submitted by November 30, 2010.

* * * * *

(3) All reports shall be submitted on forms and following procedures specified by the Administrator, shall include a statement that volumes reported to the Administrator under this section are in substantial agreement to volumes reported to the Internal Revenue Service (and if these volumes are not in substantial agreement, an explanation must be included) and shall be signed and certified by a responsible corporate officer of the reporting entity.

* * * * *

■ 16. Section 80.602 is amended by revising paragraphs (a)(2)(iii), (b) introductory text, (d), and (e), and adding paragraph (f) to read as follows:

§ 80.602 What records must be kept by entities in the NRLM diesel fuel and diesel fuel additive production, importation, and distribution systems?

(a) * * *

(2) * * *

(iii) The results of the tests for sulfur content (including, where applicable, the test results with and without application of the adjustment factor under § 80.580(d)), for cetane index or aromatics content, dye solvent red 164, marker solvent yellow 124 (as applicable), and the volume of product in the storage tank or container from which the sample was taken.

* * * * *

(b) Additional records to be kept by refiners and importers of NRLM diesel fuel. Beginning June 1, 2007, or June 1, 2006, pursuant to the provisions of § 80.535 or § 80.554(d), any refiner producing diesel fuel subject to a sulfur standard under § 80.510, § 80.513, § 80.536, § 80.554, § 80.560, or § 80.561, for each of its refineries, and any importer importing such diesel fuel separately for each facility, shall keep records that include the following information for each batch of NRLM diesel fuel or heating oil produced or imported:

* * * * *

(d) Additional records that must be kept by mobile facilities. Any registered mobile facility must keep records of all contracts from any contracted components (*e.g.* tank truck, barge, marine tanker, rail car, etc.) of each of its registered mobile facilities.

(e) Length of time records must be kept. The records required in this section shall be kept for five years from the date they were created, except that records relating to credit transfers shall be kept by the transferor for five years from the date the credits were transferred, and shall be kept by the transferee for five years from the date the credits were transferred, used or terminated, whichever is later.

(f) Make records available to EPA. On request by EPA, the records required in this section must be made available to the Administrator or the Administrator's representative. For records that are electronically generated or maintained, the equipment and software necessary to read the records shall be made available, or if requested by EPA, electronic records shall be converted to paper documents which shall be provided to the Administrator's authorized representative.

[FR Doc. 05–22807 Filed 11–21–05; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 146

[FRL–7999–7]

Underground Injection Control Program—Revision to the Federal Underground Injection Control Requirements for Class I Municipal Disposal Wells in Florida

AGENCY: Environmental Protection Agency.

ACTION: Final rule.

SUMMARY: Today's rule amends the current Federal Underground Injection Control (UIC) requirements by providing a regulatory alternative to owners and operators of Class I municipal disposal wells in specific areas of Florida that have caused or may cause movement of fluid into an Underground Source of Drinking Water (USDW). Because operation of Class I wells with fluid movement into a USDW is prohibited by Federal UIC regulations, this new rule offers owners and operators of municipal disposal wells in certain counties in Florida the ability to continue to operate their wells provided they meet additional wastewater treatment requirements. These new treatment requirements, which apply only to injection operations in certain counties of Florida, are designed to provide an equivalent level of protection to USDWs that is afforded by the no-fluid-movement standard.

DATES: This regulation is effective December 22, 2005. For purposes of judicial review, this final rule is promulgated as of 1 p.m., Eastern time on December 6, 2005, as provided in 40 CFR 23.7.

ADDRESSES: The official public docket for this rule is located at the U.S. Environmental Protection Agency (EPA), Region 4 Library (9th Floor), Sam Nunn Atlanta Federal Center, 61 Forsyth Street, SW., Atlanta, GA 30303–8960. The docket is available for inspection from 8 a.m. to 3:30 p.m., Eastern time, Monday through Friday, excluding legal holidays. For information on how to access Docket materials, please call (404) 562–8190 and refer to the Florida UIC docket.

FOR FURTHER INFORMATION CONTACT: For technical inquiries, contact Nancy H. Marsh, Ground Water & UIC Section, U.S. EPA Region 4, 61 Forsyth Street, SW., Atlanta, GA 30303–8960 (phone: 404–562–9450; E-mail: *marsh.nancy@epa.gov*) or Lee Whitehurst, Office of Ground Water and Drinking Water, U.S. EPA, EPA East, 1200 Pennsylvania Avenue, NW.,Washington, DC 20460 (phone: 202–564–3896; E-mail: *whitehurst.lee@epa.gov*). For general information, contact the Safe Drinking Water Hotline, at 800–426–4791. The Safe Drinking Water Hotline is open Monday through Friday, excluding legal holidays, from 9 a.m. to 5 p.m., Eastern time.

SUPPLEMENTARY INFORMATION:

Table of Contents

I. General Information
- A. Who Are Regulated Entities?
- B. Abbreviations and Acronyms Used in the Preamble and Final Rule

II. Background
- A. Why Is EPA Taking This Regulatory Action?
- B. Statutory and Regulatory Framework
- C. Requirements To Prevent Fluid Movement
- D. Domestic Wastewater Disposal in Florida Through Class I Wells
- E. July 7, 2000 Proposed Rule
- 1. Option 1: Advanced Wastewater Treatment (AWT) with a Non-endangerment Demonstration.
- 2. Option 2: In-depth Hydrogeologic Demonstration and Advanced Treatment, as Necessary

EXHIBIT 12

F. 2003 Relative Risk Assessment
1. Relative Risk Assessment Question 1: What Level of Treatment and Disinfection Is Provided for the Management Options of Treated Wastewater in South Florida?
2. Relative Risk Assessment Question 2: What Stressors Remain (After Treatment) That May Be a Concern for the Management Options of Treated Wastewater in South Florida?
3. Relative Risk Assessment Question 3: What Exposure Pathways Are (or May Be) of Significance for the Management Options of Treated Wastewater in South Florida?
4. Relative Risk Assessment Question 4: What Is the Overall Estimate of Risk for the Management Options of Treated Wastewater in South Florida?
5. Relative Risk Assessment Question 5: What Are the Important Data or Knowledge Gaps for Deep Well Injection?
G. May 5, 2003, Notice of Availability and Notice of Data Availability
1. NODA Question 1: What Is the Appropriate Level of Wastewater Treatment Prior to Injection?
2. NODA Question 2: Is it Feasible To Predict Movement of Fluids Through Hydrogeologic Demonstrations?
3. NODA Question 3: Have Some Deep Wells Been Misclassified as Class I, When They Are Actually Class V?
III. Summary of Public Comments
A. Comments on the July 7, 2000, Proposed Rule
1. Selection of Option 1, Option 2, or a Combination of Both
2. Appropriate Level of Wastewater Treatment
3. Need for Pretreatment
4. Feasibility of Hydrogeologic Demonstrations to Predict Movement of Fluids
5. Monitoring Requirements
6. Rule Applicability
7. Suitability of Florida Geology for Domestic Wastewater Disposal Through Class I Wells
B. Comments on the Notice of Data Availability and the Relative Risk Assessment
1. Appropriate Level of Wastewater Treatment Prior to Injection
2. Feasibility of Hydrogeologic Demonstrations To Predict Movement of Fluids
3. Class I or Class V
IV. Explanation of Today's Action
A. Objectives and Approach
B. Operating Requirements
1. Selected Approach
a. Rationale for Requiring Pretreatment of Wastewater
b. Rationale for Requiring Secondary Treatment of Wastewater
c. Rationale for Using Florida Definition of High-Level Disinfection
d. Rationale for Not Requiring the Removal of Other Contaminants
e. Rationale for Phasing In the New Treatment Over Time
2. In-Depth Hydrogeologic Demonstrations
C. Monitoring Requirements
D. Rule Applicability
1. How Will the New Rule Affect New Wells?
2. What Florida Counties Are Covered by the Final Rule?
E. Reclassification of Wells that Have Caused Fluid Movement
V. Cost of the Rule
VI. Statutory and Executive Order Reviews
A. Executive Order 12866: Regulatory Planning and Review
B. Paperwork Reduction Act
C. Regulatory Flexibility Act
D. Unfunded Mandates Reform Act
E. Executive Order 13132: Federalism
F. Executive Order 13175: Consultation and Coordination With Indian Tribal Governments
G. Executive Order 13045: Protection of Children From Environmental Health & Safety Risks
H. Executive Order 13211: Actions That Significantly Affect Energy Supply, Distribution, or Use
I. National Technology Transfer Advancement Act
J. Congressional Review Act

I. General Information

A. Who Are Regulated Entities?

This regulation is limited in application to the owners and/or operators of existing Class I underground injection wells that inject domestic wastewater effluent in certain parts of Florida. It is limited geographically to wells in the following counties: Brevard, Broward, Charlotte, Collier, Flagler, Glades, Hendry, Highlands, Hillsborough, Indian River, Lee, Manatee, Martin, Miami-Dade, Monroe, Okeechobee, Orange, Osceola, Palm Beach, Pinellas, St. Johns, St. Lucie, Sarasota, and Volusia. These counties are included in this rule because they have the unique geologic conditions that are predominated by carbonate rocks. Such rocks commonly contain fractures, faults, and solution cavities that provide preferential paths for the movement of underground fluids.

Class I injection wells are wells that inject fluids beneath the lowermost formation containing, within one-quarter mile of a well bore, a USDW (40 CFR 144.6(a)). Class I wells can be used to inject hazardous, industrial, or municipal wastes. Class I municipal disposal wells inject treated wastewater from publicly or privately owned and operated facilities that treat domestic wastewater (commonly referred to as sanitary wastewater or sewage), which is principally derived from dwellings, business buildings, and institutions. Treated wastewater from industrial facilities, often controlled through pretreatment standards, may also be found in this wastewater. Currently, Class I municipal disposal wells are located only in the State of Florida. Specific regulated categories and entities include:

Category	Examples of entities
Municipalities and Local Government	Class I municipal disposal wells disposing of domestic wastewater effluent in certain parts of Florida
Private	Class I municipal disposal wells disposing of domestic wastewater effluent in certain parts of Florida.

This table is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be regulated by this action. This table lists the types of entities that EPA is now aware could potentially be regulated by this action. Other types of entities not listed in the table could also be regulated. To determine whether your facility is regulated by this action, you should carefully examine the applicability criteria in 40 CFR 146.15 of the rule. If you have questions regarding the applicability of this action to a particular entity, consult one of the persons listed in the preceding **FOR FURTHER INFORMATION CONTACT** section.

B. Abbreviations and Acronyms Used in the Preamble and Final Rule

AWT Advanced Wastewater Treatment
BOD Biochemical Oxygen Demand
CFR Code of Federal Regulations
EPA Environmental Protection Agency
F.A.C. Florida Administrative Code
FDEP Florida Department of Environmental Protection
ICR Information Collection Request
MGD Million Gallons per Day
NDWAC National Drinking Water Advisory Council
NOA Notice of Availability
NODA Notice of Data Availability
NTTAA National Technology Transfer and Advancement Act
O&M Operations and Maintenance
OMB Office of Management and Budget
RCRA Resource Conservation and Recovery Act

RFA Regulatory Flexibility Act
SBREFA Small Business Regulatory Enforcement Fairness Act
SDWA Safe Drinking Water Act
TDS Total Dissolved Solids
TSS Total Suspended Solids
USDW Underground Source of Drinking Water
UIC Underground Injection Control
UMRA Unfunded Mandates Reform Act

II. Background

A. Why Is EPA Taking This Regulatory Action?

In the early 1980's EPA found that some Class I municipal wells in specific areas in Florida caused or may cause fluid movement into an Underground Source of Drinking Water (USDW). On July 7, 2000, EPA proposed a revision to the UIC regulations whereby continued injection would be allowed only if owners or operators met certain additional wastewater treatment requirements. EPA requested public comment on options for providing additional wastewater treatment at municipal disposal facilities in certain counties in Florida that have or may cause fluid movement.

As part of EPA's FY 2000 appropriations bill, Congress asked EPA to conduct a relative risk assessment of deep well injection, ocean disposal, surface discharge, and aquifer recharge of treated effluent in South Florida. EPA published the Relative Risk Assessment of Management Options for Treated Wastewater in South Florida in April 2003. In the Relative Risk Assessment, EPA reported that results from ground water monitoring around some Class I municipal disposal wells in Florida confirm that fluids have migrated out of the permitted injection zone and, in some cases, into USDWs. EPA also found that the full extent of USDWs contamination is not known because the fate and transport of pathogens contained in injected effluent is especially difficult to define even with the most sophisticated ground water modeling or monitoring.

On May 5, 2003, EPA issued a Notice of Availability (NOA) announcing the availability of the Relative Risk Assessment and a Notice of Data Availability (NODA), requesting public comment on how the findings in the Relative Risk Assessment should inform this final rulemaking.

Without today's rule, the no-fluid-movement requirement would remain the only available approach for regulating Class I municipal disposal wells in Florida, regardless of the level of wastewater treatment prior to injection. Enforcing this approach would, in effect, require owners and operators to shut these wells down because wastewater isolation from USDWs cannot be ensured. Shutting down the injection wells would, in turn, force the municipal wastewater to be managed by other means, which could increase the risks to surface water and coastal ecosystems.

As an alternative, EPA has chosen, for Class I municipal disposal wells in certain parts of Florida, another approach that it believes will be as effective as confinement in protecting USDWs from the contaminants in the wastewater. This alternate approach involves the rigorous control of the quality of the injected fluids. Under this approach, the movement of fluids into USDWs, whether known or suspected, should not endanger the USDWs because the quality of the wastewater has been treated to a level that is no longer a threat to USDWs. Today's action shifts the endangerment protection strategy employed for Class I municipal disposal wells in certain parts of Florida from the no-fluid-movement standard to an alternate approach that relies on treatment of wastewater before it is injected. This shift, however, does not undercut the protection of USDWs or weaken the UIC Program requirements. Although facility owners and operators in the designated counties must meet new treatment requirements to continue injecting without violating the no-fluid-movement standard, they must also comply with all other applicable UIC requirements to ensure that their injection wells do not endanger USDWs.

In the Relative Risk Assessment's evaluation of injection practices in Florida, pathogens were identified as the contaminant in municipal wastewater that presents the greatest risk to USDWs. High-level disinfection of this municipal wastewater is an effective method for inactivating these pathogens.

Therefore, in today's rule, EPA amends the current Federal UIC regulations to allow owners and operators of Class I municipal disposal wells in specific areas of Florida to continue using their wells, even if they have caused or may have caused movement of fluid into a USDW, provided they meet new requirements to treat their municipal wastewater with pretreatment, secondary treatment, and high-level disinfection.

B. Statutory and Regulatory Framework

Class I underground injection wells are regulated under the authority of Part C of the Safe Drinking Water Act (''SDWA'' or ''the Act'') (42 U.S.C. 300h *et seq.*). The SDWA is designed to protect the quality of drinking water sources in the United States and prescribes that:

> Underground injection endangers drinking water sources if such injection may result in the presence in underground water which supplies or can reasonably be expected to supply any public water system of any contaminant, and if the presence of such contaminant may result in such system's not complying with any national primary drinking water regulation or may otherwise adversely affect the health of persons. (Section 1421(d)(2) of the SDWA, 42 U.S.C. 300h(d)(2).)

Part C Protection of Underground Sources of Drinking Water of the Act specifically mandates the regulation of underground injection. The Agency has promulgated a series of UIC regulations under this authority at 40 CFR parts 144 through 147. The chief goal of any Federally approved UIC Program (whether administered by the State or EPA) is the protection of USDWs. This includes not only those aquifers which are presently being used for drinking water, but also those which can reasonably be expected to be used in the future. EPA has established through its UIC regulations that underground aquifers with less than 10,000 mg/l total dissolved solids (TDS) and which contain a sufficient quantity of ground water to supply a public water system are USDWs. (40 CFR 144.3)

Section 1421 of the Act requires EPA to propose and promulgate regulations specifying minimum requirements for effective State programs to prevent underground injection that endangers drinking water sources. EPA promulgated administrative and permitting regulations, now codified in 40 CFR parts 144 and 146, on May 19, 1980 (45 FR 33290), and technical requirements, in 40 CFR part 146, on June 24, 1980 (45 FR 42472). The regulations were subsequently amended on August 27, 1981 (46 FR 43156), February 3, 1982 (47 FR 4992), January 21, 1983 (48 FR 2938), April 1, 1983 (48 FR 14146), July 26, 1988 (53 FR 28118), December 3, 1993 (58 FR 63890), June 10, 1994 (59 FR 29958), December 14, 1994 (59 FR 64339), June 29, 1995 (60 FR 33926), December 7, 1999 (64 FR 68546), May 15, 2000 (65 FR 30886), and June 7, 2002 (67 FR 39584). Section 1421(b)(3)(A) of the Act also provides that EPA's UIC regulations shall ''permit or provide for consideration of varying geologic, hydrological, or historical conditions in different States and in different areas within a State.''

When EPA promulgated its UIC regulations, it defined five classes of injection wells in 40 CFR 144.6. Class I wells are defined as wells which inject

fluids beneath the lowermost formation containing, within one-quarter mile of the well bore, a USDW. Class I wells can be hazardous waste or other industrial or municipal disposal wells. (Hazardous waste injection must meet additional Resource Conservation and Recovery Act (RCRA) requirements. See 40 CFR part 148. Class I municipal disposal wells can be owned by public and private entities, as discussed above.

Section 1422 of the Act provides that States may apply to EPA for national primary enforcement responsibility to administer the UIC program. Those States receiving such authority are referred to as ''Primacy States.'' Florida received national primary enforcement responsibility for the UIC program for Class I, III, IV, and V wells on March 9, 1983. UIC regulations specific to Florida's primacy program are established in 40 CFR part 147, Subpart K. For the remainder of this preamble, reference to the UIC Program ''Director'' means the Secretary of the Florida Department of Environmental Protection (FDEP). Currently, all UIC Programs in Indian Country for Florida are directly implemented by EPA. It is EPA's intent that the provisions of this regulation apply to Class I municipal disposal wells in Indian Country within the counties identified in 40 CFR 146.15(f). At this time, there are no known Class I municipal disposal wells in Florida in Indian Country.

C. Requirements To Prevent Fluid Movement

When EPA promulgated its regulations for the UIC program, it established different requirements for each class of wells, based upon the uses and risks of various types of wells. All classes of wells are required to comply with 40 CFR 144.12(a) which states:

> No owner and/or operator shall construct, operate, maintain, convert, plug, abandon, or conduct any other injection activity in a manner that allows the movement of fluid containing any contaminant into underground sources of drinking water, if the presence of that contaminant may cause a violation of any primary drinking water regulation under 40 CFR part 142 or may otherwise adversely affect the health of persons.

Then, for Class I, II, and III wells, 40 CFR 144.12(b) more specifically provides that:

> If any water quality monitoring of an underground source of drinking water indicates the movement of any contaminant into the underground source of drinking water, except as authorized under 40 CFR part 146, the Director shall prescribe such additional requirements for construction, corrective action, operation, monitoring, or reporting (including closure of the injection well) as are necessary to prevent such movement.

In contrast to subsection (a), which, for all classes of wells, prohibits fluid movement that may endanger USDWs, 40 CFR 144.12(b) requires for Class I, II, and III wells that a State or Federal UIC Program Director, upon detection of contaminant movement into a USDW, prescribe requirements to prevent any such movement, regardless of whether the movement may endanger the USDW.

In addition to 40 CFR 144.12(b), EPA established technical and other requirements for specific classes of wells in Parts 144 and 146 regulations. Parts 144 and 146 regulations address siting, construction, operation, and closure of wells. Parts 144.12(b) and the specific technical requirements of parts 144 and 146 regulate the activities through which fluid movement may result and impose requirements designed to ensure that Class I, II, and III wells will not endanger USDWs by prohibiting movement of any fluid into the USDW.

D. Domestic Wastewater Disposal in Florida Through Class I Wells

Beginning more than 20 years ago, municipalities in Florida began to pursue the use of underground injection as an alternative to surface disposal of treated wastewater from domestic wastewater treatment facilities. Underground injection technology was employed to relieve stress to surface water environments because it was technologically feasible to inject large volumes of wastewater into deep permeable and transmissive formations. Through technical and monetary assistance, EPA supported construction of many of these facilities in an effort to safeguard surface waters. Through injection technology, domestic wastewater facilities have been able to dispose of large quantities of domestic effluent, with the resulting benefit of reducing impacts to surface ecosystems. Wells at facilities that inject domestic wastewater into wells below the lowermost USDW are considered to be Class I municipal disposal wells, and in Florida such wells inject into zones ranging from 650 to 3,500 feet below the land surface.

The volumes of domestic wastewater permitted for injection at Class I municipal disposal well facilities presently range from one well with less than one million gallons per day (MGD) at the Gasparilla Island Water Utilities to 17 wells with about 110 MGD at Miami-Dade Water & Sewer Department, South District Wastewater Treatment Plant. Florida requires that domestic wastewater must, at a minimum, be treated to secondary wastewater treatment standards (see 40 CFR part 133). At the time Florida permitted the currently operating Class I municipal disposal wells, characterization of the geology indicated that there was adequate confinement to isolate the injection fluids from any USDWs. Because it was thought there was adequate confinement, it was believed that injection fluids would never migrate upwards into the shallower geologic formations containing USDWs.

The current injection and confining zones in peninsular Florida exist in what is known as the Floridan Aquifer System. This system is made up of carbonate rocks. The uppermost geologic formations of the Floridan Aquifer System, as well as formations above the Floridan Aquifer, are USDWs. The porosity and permeability variations of the carbonate rocks of peninsular Florida and the existence of fractures within the formation determine their confining ability. The porosity varies greatly, even within the same horizon or geological deposit of a particular time. Monitoring of injection operations over the past several years has indicated that some deep geologic zones provide less confinement between formations than was originally thought.

It now appears, from recent well monitoring data, that upward fluid movement from some Class I municipal disposal operations occurs in Florida because the injection fluid from Class I municipal disposal wells has a lower density (lower TDS) than the native formation fluids. This tends to cause the less dense injection fluids to rise to the top of the injection zone preferentially through fractures that may exist within the formations and above the injection zone if migration pathways, such as fractures, exist. Movement of injected fluid into USDWs either has been confirmed or is suspected at eight facilities, as evidenced by levels of nitrates and ammonia, as well as significant changes in dissolved solids concentrations. (The preferential flow that leads to the movement of fluid with nitrates and ammonia can also lead to the presence of pathogens.) At an additional eight facilities, there is evidence of movement outside of the injection zone, though not into USDWs.

E. July 7, 2000 Proposed Rule

On July 7, 2000, EPA proposed revisions to the UIC regulations that would allow continued wastewater injection by existing Class I municipal disposal wells that have caused or may cause movement of contaminants into USDWs in specific areas of Florida (65

FR 42234). Continued injection would be allowed only if owners or operators met certain additional requirements that provide adequate protection for USDWs. EPA co-proposed two primary options for the additional requirements:

1. Option 1: Advanced Wastewater Treatment (AWT) With a Non-Endangerment Demonstration

The authorization to inject under Option 1 would have required that the owner and/or operator of a Class I municipal disposal well injecting domestic wastewater effluent treat the wastewater by advanced treatment methods and high-level disinfection and demonstrate that injection would not cause fluids that exceed the national primary drinking water regulations or other health-based standards to enter the USDW. The non-endangerment demonstration would focus on any contaminants that still exceed national drinking water regulations or other health-based standards after wastewater treatment. In the proposal, EPA solicited public comment on the appropriateness of this option, as well as the appropriate level of wastewater treatment, nutrient removal, and high-level disinfection that should be required if Option 1 is selected. The alternatives proposed were:

Treatment to 10–24 mg/l biochemical oxygen demand (BOD) with disinfection;

Treatment to 10–24 mg/l BOD with disinfection and nutrient removal;

Treatment to <10 mg/l BOD with disinfection;

Treatment to <10 mg/l BOD with disinfection and nutrient removal.

2. Option 2: In-Depth Hydrogeologic Demonstration and Advanced Treatment, as Necessary

The authorization to inject under Option 2 would have required that the owner and/or operator of a Class I municipal disposal well injecting domestic wastewater effluent provide a hydrogeologic demonstration that the injection operation would not cause the USDW to exceed national primary drinking water regulations or other health-based standards. EPA anticipated that this hydrogeologic demonstration would be an extensive evaluation, similar in detail to those required for a RCRA land ban no-migration petition, and consist of an analysis of the contaminants in wastewater prior to injection, include monitoring data from deep wells at the base of the USDW, and also include detailed hydrogeologic modeling of vertical and horizontal fluid transport in the injection zone and USDWs. If it was anticipated that the fluids may enter the USDW, the demonstration would have to show that the fluids would not cause the USDW to exceed primary drinking water regulations in 40 CFR part 141 or other health-based standards. Operators who could not successfully demonstrate that the injection operation meets these criteria would have been required to treat their injectate to address the contaminants of concern and satisfy additional requirements proposed to be added in a new 40 CFR 146.15(d). This second option also proposed a provision whereby all facilities qualifying for authorization to inject under this option would be required to install advanced wastewater treatment and high-level disinfection by 2015.

EPA proposed to limit the applicability of the rule to existing Class I municipal disposal wells that have caused or may cause fluid movement into USDWs in specific counties and under certain geologic conditions in Florida. The proposed counties were: Brevard, Broward, Charlotte, Collier, Flagler, Glades, Hendry, Highlands, Hillsborough, Indian River, Lee, Manatee, Martin, Miami-Dade, Monroe, Okeechobee, Orange, Osceola, Palm Beach, Pinellas, St. Johns, St. Lucie, Sarasota, and Volusia. These counties were targeted in the proposal because they have the unique geologic conditions that are predominated by carbonate rocks discussed previously. The counties were selected using a map adapted from Florida Geological Survey map series 94 ''Potential Subsurface Zones for Liquid-Waste Storage in Florida,'' created by James A. Miller of the United States Geological Survey in 1979. The proposed geological conditions were those where the injection and confining zones are both in the Floridan Aquifer, and no clastic confining unit separates the injection zone from the lowermost USDW. See United States Geological Survey's Web site for specific information on Florida's geology at *http://www.usgs.gov* or at *http://www.dep.state.FL.us/geology/.*

EPA requested comment on a range of issues associated with this proposal, including the following: (1) Should the Agency select Option 1 or 2, or, if it would be more appropriate, select a combination of both options? (2) What is the appropriate level of wastewater treatment, if Option 1 were selected? (3) What is the need to require pretreatment as an additional condition of authorization under the rule, and is it necessary to extend the pretreatment standards presently required by the State to injection facilities with less than 5 MGD? (4) Are owners and operators able to provide the kind of hydrogeologic and other information necessary for a successful hydrogeologic demonstration under Option 2? (5) Is there a need for any additional monitoring requirements for the final rule? (6) Is it appropriate to make the rule applicable only to existing wells (not new wells) and only to the proposed list of counties? (7) Is the Florida geology suitable for domestic wastewater disposal through Class I injection wells?

Following publication of the proposed rule, EPA held a series of public meetings during the comment period. These meetings provided an opportunity for interested parties to submit oral comments on the proposal. Two public meetings were held on August 22, 2000, in Tampa, Florida, and an additional two meetings were held on August 24, 2000, in West Palm Beach, Florida.

The written comments submitted on the proposed rule and the oral comments provided during the public meetings mirror each other. EPA has carefully considered all of these comments and has responded to them in full in the comment response document for the proposal, which is part of the record for this final rule. These comments are also summarized in Section III.A and factored into the Agency's final decisionmaking discussed in Section IV of today's preamble.

F. 2003 Relative Risk Assessment

As noted previously, following the July 7, 2000, proposal, Congress included the following provision as part of EPA's fiscal year 2000 appropriations bill: ''Within available funds, the conferees direct EPA to conduct a relative risk assessment of deep well injection, ocean disposal, surface discharge, and aquifer recharge of treated effluent in South Florida, in close cooperation with the Florida Department of Environmental Protection and South Florida municipal water utilities.'' Because this directive came at a time when EPA's work on the July 7, 2000, proposal was substantially complete, the Agency decided to proceed with the proposal and the relative risk assessment along separate but converging paths. EPA initiated and conducted the relative risk assessment with the intent of using relevant findings from the assessment to inform the final rulemaking. EPA published the Relative Risk Assessment of Management Options for Treated Wastewater in South Florida (EPA 816–R–03–010) in April 2003.

The methodology for the assessment involved a process of investigating the

four very different wastewater disposal options: deep well injection, aquifer recharge, discharge to ocean outfalls, and discharge to other (non-ocean) surface water bodies. Each option has its own specific stressors (hazards), exposure pathways, receptors, and potential effects. Parameters that are relevant to one particular disposal option are not necessarily relevant to the other three. Therefore, a strictly quantitative comparison between the four options was not possible.

Instead, EPA conducted what is termed a relative risk assessment to both assess the risks associated with each disposal method and allow comparisons. Individual risk assessments were completed for each wastewater disposal option and the risks associated with each were characterized. The risks and risk factors identified for each specific disposal option were then evaluated and described. Overall comparisons and conclusions were then presented as relative risk assessment matrices.

The Relative Risk Assessment addresses five key questions specifically related to deep well injection: (1) What level of treatment and disinfection is provided for deep well injection? (2) What stressors remain (after treatment) that may be a concern for deep well injection? (3) What exposure pathways are (or may be) of significance for deep well injection? (4) What is the overall estimate of risk for deep well injection? (5) What are the important data or knowledge gaps for deep well injection? The significant findings of the Relative Risk Assessment pertaining to deep well injection are contained in the report and are summarized below. (See the Relative Risk Assessment document for details on the other disposal options.)

1. Relative Risk Assessment Question 1: What Level of Treatment and Disinfection Is Provided for the Management Options of Treated Wastewater in South Florida?

All facilities that manage municipal wastewater by deep well injection in Florida are required by Florida law to provide at least secondary treatment of the wastewater prior to injection. In addition, utilities that employ deep well injection must maintain, as a contingency, disinfection capability, per F.A.C 62–500.540(1), but many do not disinfect treated effluent prior to injection. For example, treatment of wastewater that is injected by Class I municipal disposal wells in Miami-Dade and Brevard Counties consists of secondary treatment with no disinfection, although backup disinfection capability is required. In contrast, in Pinellas County, wastewater is treated to more stringent reclaimed water standards before being discharged into Class I municipal disposal wells, because the Class I wells are used to dispose of reclaimed water during periods of wet weather. Reclaimed water standards, as specified by the State of Florida, include secondary treatment plus a variety of techniques to remove microorganisms, including filtration and high-level disinfection. Filtration before disinfection serves to increase the ability of the disinfection process to inactivate viruses and other pathogens. Filtration also serves as the primary means for removing protozoa, such as *Cryptosporidium* and *Giardia.*

2. Relative Risk Assessment Question 2: What Stressors Remain (After Treatment) That May Be a Concern for the Management Options of Treated Wastewater in South Florida?

''Stressors'' include chemical or biological agents that may cause adverse effects if exposure levels are high enough. The Relative Risk Assessment describes the human health and ecological health stressors that may be found in wastewater effluent after it has been treated and that may pose a risk.

In cases where injectate has received secondary treatment only, microorganisms are generally not inactivated prior to deep well injection in Florida. When used, disinfection serves to inactivate bacteria and viruses, especially when the wastewater is sufficiently filtered prior to disinfection. Protozoan pathogens (e.g., *Cryptosporidium* and *Giardia*) may still be present if the wastewater is not filtered. Disinfection (or chlorination) byproducts such as trihalomethanes may also be present in some wastewater, although no data are available to suggest that such byproducts are a serious concern for deep well injection or any of the other wastewater management options studied.

Nutrients (e.g., nitrogen and phosphorus) can potentially stimulate the production of algae, which can lead to adverse side effects such as eutrophication, should the stressors reach surface water. Nitrogen is the primary nutrient of concern for Class I injection, because of its mobility in ground water.

3. Relative Risk Assessment Question 3: What Exposure Pathways Are (or May Be) of Significance for the Management Options of Treated Wastewater in South Florida?

An ''exposure pathway'' is the course a stressor takes from a source of release to an exposed organism. It is defined by the different environmental media through which a stressor migrates (e.g., air, surface water, ground water) as well as the mechanism by which an organism is actually exposed (e.g., inhalation, drinking, topical contact).

There are documented impacts to USDWs resulting from deep well injection in Florida, which raise concerns about potential human exposures via the drinking water pathway. Beginning in the late 1980s, ground water monitoring wells at 16 of the 42 municipal facilities that utilize Class I deep well injection in Florida began to detect the movement of fluid outside of the permitted injection zones. As previously mentioned, movement of contamination into USDWs either has been confirmed or is suspected at eight facilities.

There is also the potential for contaminants released by deep well injection to migrate through the subsurface and discharge into marine and/or surface waters, where they could pose risk via other pathways if loadings were sufficiently large. However, the risk assessment concluded that it is unlikely that stressors would migrate from the deep injection zone to surface water.

4. Relative Risk Assessment Question 4: What Is the Overall Estimate of Risk for the Management Options of Treated Wastewater in South Florida?

Although the report does not quantify risks, it offers conclusions about the relative risks of the four wastewater management options studied and about the various factors that influence risks to human and ecological health.

What Is the Human Health Risk?

The human health risks associated with deep well injection (as well as the other three wastewater management options studied in the risk assessment) were found to be generally low. However, the degree of wastewater treatment, and in particular the level of disinfection and filtration of pathogenic microorganisms, is a major risk driver. There is greater potential risk associated with wastewater that is not filtered and then disinfected to inactivate bacteria and viruses, and not filtered to remove protozoan pathogens, such as *Cryptosporidium* and *Giardia.* This suggests higher relative risks for deep well injection operations that do not filter and disinfect wastewater and the risk is highest in situations where the injectate migrates through fractures, and solution cavities. The risk associated with microorganisms being released by deep well injection would be mitigated somewhat in situations where the

injection is dominated by porous media flow, characterized by long travel times to current or potential drinking water sources and fine pore spaces capable of retaining microorganisms.

Once microorganisms and other stressors are released to the environment, the level of risk they pose to human health depends largely on how likely they are to enter drinking water supplies. The Relative Risk Assessment suggests that deep well injection has a higher risk than the other wastewater management options because current UIC regulatory requirements for pathogen removal/inactivation are less stringent.

What Are the Ecological Health Risks?

Overall, the risk to surface water ecosystems is low when treated wastewater is managed by deep well injection. The potential for damage may be higher where treated wastewater is released in proximity to surface water with previously impaired water quality, which is the case for many surface water bodies in Florida. Deep well injection could also pose a risk to marine ecology if contaminants can readily migrate and discharge to offshore waters. Although some uncertainty remains, the potential for this actually to happen in Florida and pose a real threat in the ocean is believed to be unlikely. Two potential ecological effects of particular concern, should surface or ocean waters be sufficiently contaminated, include harmful algal blooms and bioconcentration of toxic contaminants in the food web. Algal blooms can cause a variety of toxic symptoms (including death) in aquatic organisms as well as nontoxic adverse effects such as clogging of gills and smothering of coral reefs and sea grass beds. Food web bioconcentration of metals and other contaminants can also cause a variety of toxic effects.

5. Relative Risk Assessment Question 5: What Are the Important Data or Knowledge Gaps for the Management Options of Treated Wastewater in South Florida?

For all four wastewater management options that were considered in the Relative Risk Assessment, EPA found that there is a lack of definitive studies in Florida that use a physical or chemical tracer or indicator to identify the source and transport pathways of stressors detected in the environment. Without more definitive tracer studies for each wastewater management option, it is difficult to assess the potential effects of local conditions on the fate and transport of treated wastewater after being released into the environment. While results from ground water monitoring around some Class I municipal disposal wells in Florida confirm that fluids have migrated out of the permitted injection zone, the full areal extent of USDW contamination is not known. The unknown degree of migration is not only because of limited availability of monitoring data, but also because the location and connectivity of natural conduits for fluid flow (fractures and solution cavities in underground formations) are difficult to predict. In addition, the rates of microbial survival, inactivation, and transport are difficult to predict. Also uncertain are the rates of microbial straining or filtration by geological materials under different fluid flow scenarios, including porous media and conduit flow. The fate and transport of pathogens is especially difficult to verify for deep well injection, even with the most sophisticated modeling or with expensive monitoring, since the receiving formations are thousands of feet underground.

G. May 5, 2003, Notice of Availability and Notice of Data Availability

On May 5, 2003, EPA issued a Notice of Availability (NOA) (68 FR 23673) announcing the availability of the Relative Risk Assessment and a Notice of Data Availability (NODA) (68 FR 23666), requesting public comment on how the Relative Risk Assessment informs this rulemaking.

Following publication of the NOA and NODA, EPA held a series of public meetings on the Relative Risk Assessment. These meetings, held during the comment period, provided an opportunity for interested parties to submit oral comments on the Relative Risk Assessment. Two public meetings were held, one in West Palm Beach, Florida on June 24, 2003, and a second in Tampa, Florida on June 25, 2003.

The comments provided at the meetings address the same issues as those submitted in writing. EPA has considered the comments provided in the meetings along with the written comments submitted during the comment period following publication of the NODA. The comment response document for the NODA, which is part of the record for this rule, summarizes all of these comments and provides EPA's responses. These comments are also summarized in Section III.A and factored into the Agency's final decisionmaking discussion in Section IV of today's preamble.

In the NODA, EPA summarized the findings of the Relative Risk Assessment, highlighting those that are most relevant findings to informing the final regulatory action, and requested comment on three issues: The appropriate level of wastewater treatment required for continued deep well injection; the feasibility of hydrogeological demonstrations for showing that injection will not cause fluids to enter USDWs; and whether some of the Class I municipal disposal wells in Florida are actually misclassified Class V wells.

1. NODA Question 1: What Is the Appropriate Level of Wastewater Treatment Prior to Injection?

In the NODA, EPA requested comment on an alternative option for defining the appropriate level of wastewater treatment required for continued injection in deep municipal disposal wells in Florida (instead of the four options included in the July 7, 2000, proposal, as listed in Section II.D above). Based on comments received on the proposed rule related to wastewater treatment, as well as findings from the Relative Risk Assessment, the NODA solicited comments on prescribing wastewater treatment requirements that conform with relevant State requirements. Under this alternative, the Agency would simply adopt, in lieu of the standards considered in the proposal, the Florida standards in Rule 62–610.460, F.A.C. (for waste treatment and disinfection applicable to reclaimed water that may come into contact with people) or the standards in Rule 62–600.540(2), F.A.C. (for ground water disposal by underground injection in Class V wells) and Rule 62–600.440(5), F.A.C. (for design and operational criteria for high-level disinfection). Specifically, EPA would require wastewater treatment that results in injected water meeting, at a minimum, secondary treatment and high-level disinfection as defined in the Florida regulations. Also, filtration would be required for total suspended solids (TSS) control prior to disinfection, which would specify that the treated wastewater not contain more than 5.0 mg/l of TSS before the application of the disinfectant. As discussed in the NODA, EPA believes that this treatment standard might offer some important advantages over the alternatives proposed on July 7, 2000. In particular, it might better address the risks associated with pathogens and it would be consistent with the standards already adopted and implemented in Florida for reclaimed water and wastewater disposed through Class V injection wells, which are part of domestic wastewater treatment systems.

In the NODA, EPA asked commenters whether this standard for advanced

treatment and high-level disinfection should be specified in the final rule. EPA also requested that commenters describe the type of treatment that would be necessary to achieve the performance standards (i.e., national primary drinking water regulations and other health-based standards) and provide any information they have on the costs of this option.

2. NODA Question 2: Is It Feasible To Predict Movement of Fluids Through Hydrogeologic Demonstrations?

In the NODA, EPA requested comment on whether the findings from the Relative Risk Assessment regarding deep well injection suggest anything about the practicability and feasibility of the approach outlined under Option 2 in the July 7, 2000, proposal. As summarized above, Option 2 would allow owners and operators to conduct hydrogeologic demonstrations to show that injection will not cause fluids that exceed any national primary drinking water regulations or other health-based standards to enter any USDW.

Based on the added findings in the Relative Risk Assessment regarding the Florida geology, EPA posed several questions in the NODA related to the uncertainties of hydrogeologic demonstrations that would be required under Option 2. In particular, EPA asked whether facilities should be granted the opportunity to conduct the demonstrations; how the UIC Program Director should address anticipated technical difficulties in his/her review of a demonstration; and how a satisfactory hydrogeological demonstration would be conducted.

3. NODA Question 3: Have Some Deep Wells Been Misclassified as Class I, When They Are Actually Class V?

Given the extent of fluid movement documented at some sites, as well as information concerning the geology and the construction of some municipal disposal wells in Florida, it is possible that some wells may have been misclassified as Class I, when they are actually Class V. According to the Federal UIC regulations, Class I wells ''inject fluids beneath the lowermost formation containing, within one quarter mile of the well bore, an underground source of drinking water'' (40 CFR 144.6(a)(2)). Class V wells are defined as wells that are not included in Class I, II, III, or IV. Typically, Class V wells release nonhazardous fluids into or above formations containing USDWs.

Separate from the issue of how Class I and Class V wells are defined, the Federal Class I and Class V UIC programs differ in their basic approach to protecting USDWs. As previously described in Section II.B, the basic standard of protection in the Class I program is to ensure that there is no movement of any contaminant into USDWs. This standard is achieved through a Class I regulatory program that focuses on the development and enforcement of stringent permit requirements, including, but not limited to, criteria for well siting, construction, and operation and maintenance. A key component of the Class I program is ensuring that adequate confinement exists between the permitted injection zone and USDWs at a given site.

Since most Class V wells release fluids either directly into or above USDWs, they by definition cause the movement of fluid, which may contain contaminants, into or above USDWs. Therefore, the basic standard of protection in the Class V program is to prevent any contaminants in the fluid from endangering USDWs. Protection efforts in the Class V program mainly focus on regulating and monitoring injectate quality to ensure that the movement of injected fluid will not contain any contaminants that may endanger USDWs. This standard is achieved through inventory and assessment requirements, additional reporting requirements, closure requirements, and other requirements (possibly including permitting requirements) believed by UIC Program staff to be necessary to protect drinking water supplies.

Information collected for the Relative Risk Assessment raises a question as to whether certain Florida municipal disposal wells should have been classified as Class V at the time they were first permitted. In particular, all of the lithologic units of the upper Floridan Aquifer in Pinellas County and the lower Floridan Aquifer in Miami-Dade consist of limestone and dolomite that have shown evidence of solution cavities and fractures. These natural conduits for fluid flow raise a question as to whether lithologic units in these aquifers are effective confining layers and whether the injection zones and overlying USDWs are in different and distinct formations, as they were believed to be when the wells were originally sited, constructed, and permitted as Class I wells.

Based on this information, the NODA requested comment on whether the findings from the Relative Risk Assessment suggest that some Florida wells may have been misclassified as Class I wells. EPA also asked whether the findings suggest that some wells in Florida may, in fact, discharge directly to (and not below) formations containing a USDW, and if the findings suggest that this misclassification should be accepted for the entire group of Florida municipal disposal wells, or only a subset.

III. Summary of Public Comments

A. Comments on the July 7, 2000, Proposed Rule

EPA received 1,181 comments in response to the proposed rule. The following sections summarize the more significant public comments on the seven main issues raised in the proposal. These comments are addressed in more detail in the comment response document available for review in the Florida UIC docket as well as in Section IV of today's preamble.

1. Selection of Option 1, Option 2, or a Combination of Both

In the proposal, EPA solicited comment on whether to select Option 1 (advanced wastewater treatment (AWT) with a non-endangerment demonstration), Option 2 (in-depth hydrogeologic demonstration and advanced treatment, as necessary), or a combination of both options.

Commenters who favor Option 1 explained that, although initially more costly, this option offers the advantage of allowing identification and avoidance of potential drinking water contamination, which would be more cost-effective than ground water remediation. One commenter offered that Option 1 should be required only if needed to meet the non-endangerment requirement. A commenter opposed to Option 1 said that even with AWT, the proposed requirements may not prevent violations of drinking water standards in USDWs.

Those commenters favoring Option 2 argued that it would be burdensome to require utilities to employ AWT immediately. They therefore suggested that AWT either should not be required at all or should be phased-in. One commenter opposing Option 2 said that facilities already perform analyses to demonstrate compliance, and geochemical modeling should be required only where actual data are not available. Another commenter opposing Option 2 said that it is unclear what geochemical modeling would accomplish.

2. Appropriate Level of Wastewater Treatment

In the proposed rule, EPA requested comment on which treatment alternative to specify in the final rule, if Option 1 were selected. Comments were

solicited on the appropriate level of BOD treatment and the need for disinfection and nutrient removal.

Commenters who favored higher levels of BOD treatment (to less than 10 mg/l) asserted that these standards would protect the environment and can be met with available cost-effective technologies. Commenters opposed to requiring BOD treatment said that it is not possible to meet the disinfection requirement with BOD levels of 10 to 24 mg/l, or that there is no technical basis for requiring those levels, since the treated wastewater is being discharged to an anaerobic environment without plant life.

Commenters who supported nutrient removal requirements said that such treatment would have environmental benefits, including protecting wetlands and endangered species. Commenters who opposed nutrient removal explained that it could adversely impact water reuse programs. These commenters also opposed setting phosphorus limitations, saying that there are no human health benefits associated with phosphorus removal.

Commenters who favored requiring AWT said that injected fluids can move into surficial aquifers or near shore surface waters, and AWT is thus needed to protect aquatic species. Commenters opposed to requiring AWT asserted that imposing health-based standards as discharge requirements is inconsistent with the SDWA and not supported by scientific data. These commenters added that injection provides effective source separation that has protected water supplies for many years and that requiring AWT would jeopardize the viability of this practice going forward. Other commenters thought that AWT is insufficient to prevent endangerment of USDWs. These commenters expressed concern that the proposal does not adequately protect USDWs from many of the substances that may be found in municipal wastewater.

3. Need for Pretreatment

EPA solicited public comment on the need for pretreatment as an additional condition of the authorization to inject, and on whether to extend the pretreatment requirements presently required by the State of Florida to injection facilities with flows of less than 5 MGD.

Commenters advocating pretreatment requirements suggested that requiring industrial users to pretreat their wastewater would reduce the chance of contaminating USDWs and reduce the costs to municipal treatment works. Several commenters advocated extending pretreatment requirements to facilities with flows of less than 5 MGD.

Commenters opposed to the pretreatment requirements cited concerns about the ineffectiveness of pretreatment programs to prevent fluid movement or protect public health.

4. Feasibility of Hydrogeologic Demonstrations To Predict Movement of Fluids

EPA solicited comment on the ability of injection well owners and operators to provide the kind of hydrogeologic and other information necessary for a successful hydrogeologic demonstration that their injectate will not cause a USDW to exceed any primary drinking water regulations or other health-based standards.

Commenters opposed to the proposed hydrogeologic demonstrations asserted that they could not accurately reflect flow responses after prolonged injection, and that EPA should not rely on them to protect USDWs. These commenters cited limitations in available knowledge of the subsurface geology of Florida and the fate of contaminants.

5. Monitoring Requirements

EPA requested comments on the proposed monitoring requirements (which would include, at a minimum, effluent monitoring and an analysis of any such contaminants following injection), and asked whether any additional monitoring requirements should be included in the final rule.

Some commenters challenged the proposed monitoring requirements, claiming that they are not adequate to prevent endangerment of ground water quality. Two commenters suggested a need to monitor for pathogens, viruses, and pharmaceuticals. Several commenters requested an increased monitoring frequency, believing that annual monitoring is insufficient to characterize the injected fluids.

Many commenters requested that EPA clarify certain aspects of the proposed monitoring requirements, including what is meant by ''other health-based standards.''

6. Rule Applicability

EPA requested comment on whether the rule should apply to existing wells only or also to new wells. Some commenters suggested that the rule apply to new and existing wells, as well as to replacement wells, and recommended that the rule apply in all counties where fluid migration could or does occur. Those commenters who opposed applying the rule to facilities that have not shown movement of fluid to USDWs expressed concern that such an approach would limit the future application of injection as a disposal technology.

In the proposal, EPA also requested comment on whether any additional (or fewer) counties in Florida should be included within the scope of the rule. No comments requesting the addition or removal of any counties were received.

7. Suitability of Florida Geology for Domestic Wastewater Disposal Through Class I Wells

Commenters provided information and background on the geology of Florida, fluid migration, and the appropriateness of wastewater injection in Florida.

Some commenters expressed concern about injection operations contaminating drinking water aquifers with a virus or pathogen, citing evidence that effluent is leaking into the Floridan Aquifer that is hydrogeologically connected to the Biscayne Aquifer, the sole source of Miami-Dade's drinking water. These commenters said that there are many unknowns about the geology of Florida and that the behavior of injected fluids cannot be accurately predicted.

Other commenters asserted that injection is a safe practice that has been taking place in Florida for decades without any documented adverse impacts to USDWs. They indicated that the injected fluid is ''freshening'' the highly saline receiving waters, and that the availability of injection as a disposal alternative has resulted in significant improvements to surface water quality in Florida. Some commenters added that, in the proposal, EPA did not adequately characterize the subsurface geology in Florida. Some commenters recognized that fluid movement is occurring, but support a rule that allows fluid movement if it is accompanied by a non-endangerment policy. These commenters added that a strict no movement policy would eliminate all injection and supply wells in the region.

B. Comments on the Notice of Data Availability and the Relative Risk Assessment

EPA received 203 comments in response to the NODA and its summary of the Relative Risk Assessment. The paragraphs below summarize the more significant comments on the three main issues raised in the NODA. The complete comment response document available for review in the Florida UIC docket addresses these comments in more detail.

1. Appropriate Level of Wastewater Treatment Prior to Injection

In the NODA, EPA asked for comment regarding the level to which wastewater should be treated before it is injected into deep wells that have caused or may cause fluid movement into a USDW. Some commenters advocated requiring treatment to drinking water standards before injection, citing concerns about pathogens migrating to aquifers and the inability of modeling to identify all pathways by which contamination could occur. Some commenters also expressed concern about the potential migration of viruses, pathogenic bacteria, and protozoa. They asserted that data show that injected fluids are migrating and, without disinfection, pathogens may survive, especially where the travel times to USDWs are short.

Some commenters advocated requiring denitrification as well. Commenters opposed to requiring advanced wastewater treatment said that current treatment requirements are adequate, and that the cost of requiring AWT all the time would be excessive. Some commenters cautioned against a ''one-size-fits-all'' approach, and suggested including case-by-case treatment requirements in permits. They added that, at most facilities, drinking water standards are already met within the aquifer and that, given the salinity of the injection zone, any water from the USDW would require reverse osmosis treatment before it is usable for drinking.

EPA also asked commenters whether treatment consistent with corresponding Florida requirements (i.e., treatment that meets the State's secondary treatment and high-level disinfection standards) is appropriate. Some commenters advocated requiring AWT in accordance with Florida's standards. Other commenters said that Florida sets differing standards based on the quality of the receiving waters, and that simply adopting the Florida standard would not resolve the issue where fluid migration is occurring.

2. Feasibility of Hydrogeologic Demonstrations To Predict Movement of Fluids

As previously described in Section II.F.2, the NODA requested comment on the practicality and feasibility of allowing facilities to conduct hydrogeologic demonstrations, given the inherent difficulties and uncertainties regarding the extent, location, and connectivity of possible natural conduits for flow identified in the Relative Risk Assessment.

Commenters who advocated the use of hydrogeological demonstrations said that such demonstrations would provide utilities needed flexibility, given the hydrogeologic variability in Florida. They added that this approach would be in line with the intent of Congress and the SDWA. These commenters added that monitoring shows that contaminants are not moving into USDWs, and that the critical point to consider is whether the USDW is endangered (rather than just that fluids are moving into USDWs).

Commenters who opposed allowing facilities to conduct hydrogeologic demonstrations said that monitoring programs cannot adequately characterize fluid movement in the subsurface, especially given the faulted and fractured geology of Florida.

Other commenters agreed that hydrogeological demonstrations should be conducted to understand the geology of the injection zone, but said that treatment should be required as well.

3. Class I or Class V

EPA solicited comment on ways to address the fluid movement that has occurred, while preventing the endangerment of USDWs. Specifically, EPA asked for comment on whether wells with fluid movement should be reclassified as Class V wells, or whether Class I or Class V requirements specific to Florida should be promulgated.

Commenters who advocated reclassifying the wells as Class V said that the injection and confining layers are sufficiently similar to be considered a single formation. These commenters were against ''blanket'' reclassification of the wells, however, saying that each well should be considered individually.

Other commenters, who were against reclassifying the wells as Class V, cited concerns that doing so would lead to greater reliance on injection as a wastewater disposal method. They asserted that some injected fluid is migrating to and impacting coral reefs, the wells are in violation of SDWA requirements, and the level of treatment specified will not protect USDWs. These commenters expressed doubt whether, given the existence of natural conduits connecting subsurface layers, the upper layer is sufficiently confining injected wastewater. They added that two subsurface layers sharing certain characteristics do not constitute a single formation.

IV. Explanation of Today's Action

This section describes today's action. It also discusses how EPA considered information in the Relative Risk Assessment and the NODA, as well as public comments received on each of these documents.

A. Objectives and Approach

Under Section 1421 of the Act, UIC regulations must prevent underground injection that endangers drinking water sources. While EPA met this statutory requirement in the past by prohibiting fluid movement, the Act authorizes other approaches as well, such as the approach used in today's rule, which requires treatment of wastewater prior to injection. The overriding objective of today's action is to ensure the protection of USDWs, which is the chief goal of the Federal UIC Program. In so doing, it is important that the rule: (1) Not undercut or unnecessarily burden the Florida UIC Program as it pertains to Class I municipal disposal wells; and (2) not transfer potential problems to other programs or increase concerns associated with the management of treated municipal wastewater by other practices, including aquifer recharge, surface water discharge, and ocean disposal.

In order to meet this last objective, EPA has concluded that it is important to maintain underground injection as a viable alternative for managing treated municipal wastewater in Florida. There are eight instances of known or suspected contamination of USDWs caused by Class I municipal disposal wells, but the Relative Risk Assessment has shown that the overall risks associated with such underground injection are low. The factors on which this determination of ''low risk'' was based include: The quality of the treated wastewater and the contaminants that are found in wastewater; the reduction in certain contaminants provided by secondary and, for some facilities, advanced treatment; the estimated time of travel for wastewater to move vertically to USDWs; and the anticipated reduction in contaminant concentration that occurs in the deep underground environment.

In comparison, the other wastewater management options EPA assessed in the Relative Risk Assessment do not offer clear environmental advantages and are more expensive than underground injection. The Relative Risk Assessment found that the other wastewater management options each pose specific (yet low) risks to human health and the environment that do not necessarily make them preferable to underground injection. For example, disposal of secondary treated wastewater into surface water or the ocean, rather than deep injection, carries nutrients that feed algae blooms that, in turn, can deplete the oxygen

necessary for plant life. Fish need plants for food to live. To limit these nutrients in critical surface water areas (such as Tampa Bay), municipalities are required to provide advanced wastewater treatment with nutrient removal, which is more expensive than underground injection, even when the effluent is treated by high-level disinfection. It is also important to note that, while ocean outfalls have not been prohibited by Florida statute or regulation, no new outfalls have been approved and constructed for more than 15 years. Therefore, it is questionable whether additional ocean disposal would even be an option, if injection were no longer allowed.

In order to continue to allow underground injection, the question becomes how to allow it and, at the same time, ensure the protection of USDWs. There are two basic approaches within the UIC Program for doing this. The first approach, which is currently employed for all Class I, II, and III wells, is to ensure that injected fluids are confined and isolated from USDWs. This approach is based on the premise that the quality of the injected fluids is poor and the movement of such fluids into a USDW is likely to endanger its use. To implement this approach, the standard of protection for Class I, II, and III wells is to prevent any movement of fluid into a USDW, as summarized in Section II.B of this preamble.

In the absence of today's rule, the requirement for no fluid movement would remain the basic approach for regulating Class I municipal disposal wells and be the requirement that owner/operators would have to meet in order to remain in operation. Enforcing this approach would, in effect, require these wells to shut down, because isolation from USDWs cannot be ensured due to the Florida geology and available monitoring data at some sites as described above. Shutting down the injection wells would in turn force the municipal wastewater to be managed by other means, which would not provide any net environmental benefits, would increase the risks to surface water and coastal ecosystems, and would increase treatment and other costs to owners and operators of domestic wastewater treatment facilities. The Relative Risk Assessment found that the other wastewater management options, including underground injection, pose a low risk to human health and the environment. Shutting down the wells would result in a different, but not necessarily better, alternative. All of this, in EPA's view, provides a compelling argument for an alternate approach.

The alternate approach, which is used when adequate confinement between the permitted injection zone and USDWs cannot be assured, is the rigorous control of the quality of the injected fluids. Under this approach, movement of fluids into USDWs is known or suspected, but that movement should not endanger the USDWs because the quality of the injectate is not a concern. This is the basic approach employed by EPA and the States for Class V wells, most of which release fluids into or above USDWs. Today's rule adopts a similar approach that relies on an appropriate level of wastewater treatment prior to injection in order to assure the protection of USDWs. While changing to this approach does represent a shift in the form of the controls employed for certain Class I municipal disposal wells in certain parts of Florida, it is not undercutting protection of USDWs, weakening the UIC Program requirements, or introducing a new standard. To the contrary, it is simply taking a standard approach long used in the UIC Program and applying it to this narrow category of Class I wells as a way to prevent endangerment where the existing regulations do not offer any flexibility.

Today's rule, therefore, provides a regulatory alternative to owners and operators of Class I municipal disposal wells in specific areas of Florida that have caused or may cause unauthorized movement of fluid into a USDW. Because operation of such wells is prohibited by existing Federal UIC regulations, the new rule offers owners and operators the ability to continue to operate their wells, provided they meet requirements to protect USDWs by treating their waste according to these requirements.

B. Operating Requirements

Today's rule provides owners and operators of Class I municipal disposal wells in certain counties of Florida whose injection has caused or may cause the movement of fluids into a USDW the option to (1) develop and implement a pretreatment program that is no less stringent than the requirements of Chapter 62–625, F.A.C. or demonstrates that they have no significant industrial users as defined in Chapter 62–625, F.A.C., and (2) treat the injected wastewater using secondary treatment in a manner that is no less stringent than the requirements of Florida Rule 62–600.420(1)(d), and use high-level disinfection in a manner that is no less stringent than the requirements of Florida Rule 62–600.440(5)(a)–(f). To continue injecting, owners and operators of facilities that have caused or may cause fluid movement into a USDW will have five years from the effective date of this rule to install the required treatment; these owners and operators have already been notified by the UIC Program Director that their injection wells have caused or may cause fluid movement into USDWs. If, at a later time, the Director determines that other Class I municipal disposal wells in the targeted areas of Florida have caused or may cause movement of fluids into USDWs, owners and operators of those wells will be so notified by the Director and will have five years from the date of that notification to install high-level disinfection. See new 40 CFR 146.15(d)(2). During the time between such notification and the time high-level disinfection becomes operational at these facilities, the Director has the authority to require additional operating requirements on a site-specific basis in order to protect USDWs.

These new provisions comprise Option 1 from the July 7, 2000, proposed rule as refined by the alternative treatment standard proposed in the May 5, 2003, NODA. Option 1 of the proposed rule proposed additional treatment, beyond secondary treatment, in the form of four suboptions. All four suboptions proposed high-level disinfection with advanced treatment as defined by two levels of BOD reduction with and without nutrient removal. The alternative treatment level in the NODA, like all of the suboptions in the proposed rule, also called for high-level disinfection. However, the alternative treatment level in the NODA called for high-level disinfection as it is currently prescribed by the State, which includes a reduction in TSS levels to 5 ppm. This TSS level is substantially equivalent to the two suboptions in the proposed rule that called for high-level disinfection and advanced treatment defined by reduction in BOD to less than 10 ppm. In selecting this option for high-level disinfection, as first prescribed in Option 1 of the proposed rule and refined in the NODA, EPA agrees with commenters who recommended that EPA require additional or enhanced treatment because of concerns for insufficient confinement, as well as uncertainties regarding the areal extent of movement of injected wastewater in the subsurface. The selected approach, therefore, requires an additional or enhanced level of treatment that will provide an effluent quality that would not endanger USDWs. As discussed in the preceding section of this preamble, an approach that focuses on effluent

quality is a standard approach used in the Federal UIC program when adequate confinement cannot be assured.

The final operating requirements, however, do not call for the non-endangerment demonstration that was included within Option 1 of the July 7, 2000, proposal. As envisioned in the proposal, this non-endangerment demonstration would have focused on any contaminants that still exceed national drinking water regulations or other health-based standards after advanced wastewater treatment. However, the proposal did not rigorously define the level of advanced treatment that would be required, instead the proposal states that ''advanced treatment is any level of treatment in excess of secondary treatment'' (65 FR 42239, July 7, 2000). At the same time, the four alternative treatment standards proposed as part of Option 1 provided numerical criteria for BOD removal, but did not provide any criteria or other specific details to define the required level of ''disinfection.'' By adopting the definition of ''high-level disinfection'' from the Florida regulations, today's final rule imposes a specific and widely accepted standard for ensuring the removal of microorganisms, which the Relative Risk Assessment (completed after the proposal) now shows are the primary contaminants of concern. As a result, EPA does not believe that the final rule needs to require a non-endangerment demonstration focusing on contaminants after treatment. EPA is confident that the problem will be adequately solved by the treatment itself. Instead, the Florida UIC Program Director is left with the flexibility that he or she currently has to require such a demonstration, or any other measure deemed necessary, to protect USDWs on a case-by-case basis.

The following subsections provide additional discussion of two key aspects of these final operating requirements. The first discusses the selected requirement for pretreatment, secondary treatment, and high-level disinfection, including the rationale for adopting the Florida standard; the rationale for not requiring the removal of BOD, nutrients, or other contaminants besides microorganisms; and the rationale for phasing in the new treatment over time. The second subsection elaborates on EPA's rationale for not adopting the hydrogeologic demonstration approach discussed in the proposal and NODA.

1. Selected Approach

The following sections outline EPA's rationale for the specific requirements in today's rule, including requiring pretreatment, secondary treatment, and high-level disinfection, as well as the rationale for not requiring the removal of other contaminants and why the new treatment will be phased in over time.

a. Rationale for Requiring Pretreatment of Wastewater. Today's rule includes requirements for owners and operators of facilities that wish to be covered by the alternative endangerment standard to comply with existing pretreatment requirements for those facilities. EPA found that almost all (14 of the 16) facilities that have caused or may cause fluid movement into a USDW already have pretreatment programs in place, and the remaining two facilities have conducted surveys indicating that they are not handling waste streams from significant industrial users. EPA believes that existing pretreatment programs at the affected facilities are adequate and necessary to ensure that a variety of contaminants that might appear in wastewater do not endanger USDWs.

EPA agrees with commenters who suggested that requiring industrial users to pretreat their wastewater would reduce the chance of contaminating USDWs and reduce the costs to municipal treatment works. EPA also agrees with several commenters who advocated extending pretreatment requirements to facilities with flows of less than 5 MGD. EPA disagrees with commenters who opposed the pretreatment requirements, and who cited concerns about the ineffectiveness of pretreatment programs to prevent fluid movement or protect public health. EPA believes that it is important for significant industrial users to pretreat their wastewater to remove those contaminants that would not be consistently removed by a municipal wastewater treatment facility before they are injected.

Therefore, today's rule requires that owners and operators develop and implement a pretreatment program that is no less stringent than the State's requirements in Florida Rule 62–625, unless they have no significant industrial users as defined in that chapter, if they wish to avail themselves of the alternative endangerment standard. The State developed these pretreatment requirements to ensure that contaminants are prevented from endangering the public. EPA is adopting pretreatment provisions consistent with those requirements under the authority of the SDWA to prevent contaminants from endangering USDWs.

b. Rationale for Requiring Secondary Treatment of Wastewater. Florida currently requires Class I municipal wastewater facilities to apply secondary treatment prior to injection, and this requirement will stay in place regardless of the addition of the high-level disinfection requirement. Applying secondary treatment, which requires BOD reduction to 25 ppm and TSS reduction to 30 ppm, is necessary for high-level disinfection to work. Without significant reduction in suspended solids that is first achieved by secondary treatment and is further addressed by filtration, the standards for compliance with the high-level disinfection standard of 5 ppm of total suspended solids in this rule could not be achieved.

EPA's July 2000 proposed rule assumed that domestic wastewater effluent injected into Class I municipal disposal wells would have been subject to secondary treatment. See new 40 CFR 146.15(c)(3). Although some commenters expressed opposition to the options for advanced treatment proposed, no commenters expressed opposition to secondary treatment. Since the State already requires secondary treatment, and all Class I municipal well facilities provide secondary treatment, no facilities would need to upgrade their plants to meet this requirement.

c. Rationale for Using the Florida Definition of High-Level Disinfection. The record supporting this rule—including available monitoring data, the Relative Risk Assessment, and public comments—provides compelling evidence that additional wastewater treatment to remove pathogenic microorganisms is needed to ensure that continued Class I municipal disposal in certain parts of Florida does not endanger USDWs. EPA agrees with concerns expressed by many commenters that the quality of secondary-treated wastewater poses a threat to USDWs in certain parts of Florida in light of information that injected fluid at some sites is not being confined to the injection zone. In particular, pathogens may remain in wastewater following secondary treatment and can threaten USDWs if injected in certain parts of Florida. As found in the Relative Risk Assessment, the degree to which pathogenic microorganisms are removed by wastewater treatment is the main factor determining the risk associated with injection.

The Relative Risk Assessment identified pathogens as being of concern not only because of their high concentration in secondary-treated wastewater, but also because of uncertainties associated with fluid movement and their fate within the subsurface of certain parts of Florida.

EPA acknowledges, as noted by some commenters, that there will be some level of pathogen die-off in the deep subsurface and that a shallow confining system may serve as a barrier to the movement of contamination in some locations. However, EPA believes that there is incomplete information about the movement and fate of pathogens in the subsurface. This lack of information prevents EPA from concluding that pathogen die-off is sufficient to protect USDWs in the areas of Florida targeted by today's rule.

Based on these concerns, EPA has determined that owners and operators of Class I municipal disposal wells in specific areas of Florida must provide high-level disinfection if their injection has caused or may cause fluid movement into a USDW. EPA has decided to adopt Florida's definition of high-level disinfection in today's rule because it effectively addresses the risk of pathogens better than any of the other proposed alternatives. It also offers the important advantage of being consistent with the standards already adopted and implemented in Florida, thereby eliminating any confusion or disruption to existing programs.

The specific definition of high-level disinfection, as detailed in Florida Rule 62–600.440(5)(a)–(f), includes requirements to: (1) Reduce total suspended solids to 5.0 mg/l or less before the application of the disinfectant to maximize disinfection effectiveness which, (2) result in an effluent with fecal coliform values that are below detectable levels in 75 percent of the samples, and that are never above 25 organisms per 100 ml in any one sample; and (3) where chlorine is used for disinfection, assure rapid and uniform mixing with a minimum dose of 1 mg/l of free chlorine for a minimum contact time of 15 minutes. EPA is confident that requiring high-level disinfection, defined in this way (no less stringent than Florida Rule 62–600.440(5)(a)–(f)), will satisfactorily address the risk associated with microbial pathogens released by Class I injection wells in the targeted areas of Florida. Viruses and bacteria will be inactivated through high-level disinfection, the effectiveness of which is ensured by operational criteria (i.e., fecal coliform limits) and the requirement to filter the wastewater beforehand. Filtration is also the accepted method for the removal of protozoa (e.g., Cryptosporidium and Giardia).

The State of Florida found, after significant public comment and evaluation by the State Department of Health, that high-level disinfection thus defined will significantly address pathogens and reduce the chance of waterborne disease. For this reason, the State allows wastewater that has been treated by high-level disinfection to be reclaimed for reuse purposes where the public has access, such as watering lawns and golf courses. In addition, Florida requires domestic wastewater systems to use high-level disinfection when they discharge effluent above or directly into USDWs using Class V wells or when they discharge to certain surface waters, such as Tampa Bay. It is important to note, however, that these standards for high-level disinfection are not equivalent to the standards that apply to drinking water. Florida requires that valves and outlets that use reclaimed water be painted purple and labeled with ''Do Not Drink'' warning signs. Reclaimed water and water injected into Class I wells that meet the standards of today's rule will have the same water quality resulting from pretreatment, secondary treatment, filtration and high-level disinfection to ensure that they will not endanger USDWs.

In contrast to the standards for high-level disinfection, Florida also has standards for basic disinfection and intermediate disinfection, which EPA believes are not appropriate for today's rule. The State requires basic disinfection for certain surface water discharge and offshore ocean disposal, or for reclaimed wastewater used for other purposes where the public will not be exposed, such as cooling water use. Basic disinfection does not limit the quantity of TSS in the effluent and requires half the chlorine dose of high-level disinfection. Facilities that provide basic disinfection must be designed to result in a fecal coliform value of not more than 200 organisms per 100 ml.

Facilities that use intermediate disinfection must be designed for rapid and uniform mixing of chlorine with a minimum dose of 1 mg/l free of chlorine for a minimum contact time of 15 minutes, as with high-level disinfection. However, no TSS limitations are set, so the facilities avoid the expense of filtration. Facilities that provide intermediate disinfection must be designed to result in not more than 14 fecal coliform values per 100 ml. In contrast, high-level disinfection treatment facilities are designed to result in zero fecal coliform values per 100 ml. Intermediate disinfection is used in a few ''middle-ground'' instances where public access is restricted but could possibly occur; high-level disinfection is required where there is public access; and basic disinfection is allowed where public access is clearly restricted. One such instance is discharge to wetlands where public access is restricted.

EPA is adopting the State's standard for high-level disinfection rather than basic or intermediate disinfection because high-level disinfection is more appropriate for effluent injected into wells that have caused or may cause fluid movement into a USDW. Such a standard applied to effluent that moves into a USDW from below is consistent with standards the State applies to effluent that is released into or above USDWs by Class V wells. Florida's definitions and standards for basic disinfection and intermediate disinfection were established by the State to apply to situations where wastewater would be isolated and not come in contact with humans. The State anticipated the possibility that humans could inadvertently come into contact with water that has achieved high-level disinfection despite warnings. The reclaimed wastewater is not intended for regular ingestion by the population and thus does not require that level of advanced treatment needed to meet drinking water standards prior to discharge. EPA believes that the injection scenario is similar to use of reclaimed water in that, because of the depths at which wastewater is injected, the possibility of inadvertent human ingestion prior to additional treatment is remote.

However, the lack of control over the movement of fluids into USDWs in certain parts of Florida and the uncertainties about the location, concentration, and survivability of waterborne pathogens injected in those areas call for the degree of disinfection and filtration that is defined by high-level disinfection. As noted above, without the filtration that goes with high-level disinfection, there is no assurance that the treatment would effectively remove pathogenic protozoa, such as Cryptosporidium and Giardia.

d. Rationale for Not Requiring the Removal of Other Contaminants. Although pretreatment, secondary treatment, and high-level disinfection will remove many contaminants that may be present in municipal wastewater, EPA agrees with commenters who said that a large variety of contaminants, such as pharmaceutical products and disinfection byproducts, that may be present in treated municipal wastewater, may not be removed.

Today's final rule does not specifically require all affected facilities to install treatment to remove these other contaminants for four main reasons: (1) The Relative Risk

Assessment found that the only contaminants that posed a potential threat were pathogenic microorganisms; (2) Class I municipal disposal wells are precluded from injecting listed or characteristically hazardous waste streams; (3) Class I municipal disposal wells are allowed to inject only wastewater that has received a level of treatment, specified in individual permits, deemed necessary by the Director to prevent endangerment; and (4) many other contaminants are addressed through EPA's existing pretreatment regulations (see Section IV.B.1.a, above) . If the Director finds that any other contaminants pose a threat to USDWs, that threat can be addressed on a site-specific basis under existing authorities.

In the July 7, 2000, notice, EPA proposed four treatment alternatives that prescribed varying levels of BOD removal. This approach seemed reasonable because BOD, along with TSS, is a universal measure for defining levels of wastewater treatment and contaminant removal. In this sense, EPA does not agree with commenters who said that BOD cannot be used as a parameter for defining the level of treatment necessary to protect drinking water. However, the Agency does acknowledge, as several commenters pointed out, that a BOD standard would not necessarily achieve the objectives of today's final rule. EPA believes that the State's definition and standards for high-level disinfection which uses a standard for fecal coliform and a TSS limit, rather than a BOD limit, sufficiently defines the level of treatment that is necessary to protect USDWs.

The July 7, 2000, notice also proposed nutrient (nitrogen and phosphorus) removal as an element of some of the treatment alternatives. However, EPA agrees with those commenters who said that nutrient removal may not be necessary based on two findings from the Relative Risk Assessment: (1) There is not strong evidence that Class I injection has caused or may cause exceedances of the nitrate MCL in USDWs; and (2) there is not strong evidence that nutrients released by Class I injection wells are migrating into surface waters. These findings do not necessarily mean that nutrients are never a potential concern, only that there is not sufficient evidence to compel a nutrient removal standard for all wells. Therefore, today's rule does not require nutrient removal. However, the Director retains the flexibility and discretion under current authority to address nutrients on a case-by-case basis if necessary to protect USDWs.

e. Rationale for Phasing In the New Treatment Over Time. EPA agrees with commenters who said that it will take time for facilities to install high-level disinfection systems. Therefore, the final rule requires owners and operators wishing to avail themselves of today's final rule's alternative endangerment standard to have high-level disinfection installed and operating within five years of the rule's effective date, if they have already been notified by the Director that they have caused or may cause fluid movement, or within five years of the time they are so notified. EPA selected five years because it is consistent with the time that has been determined to be needed to install high-level disinfection at Miami-Dade Water & Sewer Department, South District Wastewater Treatment Plant. In the meantime, the Director has the authority to require additional operating requirements on a site-specific basis to address any potential for endangerment until the additional treatment goes into operation.

2. In-Depth Hydrogeologic Demonstrations

Today's rule does not provide the option for facility owners and operators to use a hydrogeologic demonstration to show that injection either will not cause fluids to enter USDWs, or if that cannot be shown, will not cause USDWs to exceed MCLs or other health-based standards (i.e., will not endanger USDWs). This approach was originally proposed as Option 2 and discussed further in the NODA. EPA has instead determined that, where injection has caused or may cause fluid movement into USDWs, pretreatment, secondary treatment, and high-level disinfection is the only effective alternative to the ''no-movement'' standard as a means of ensuring non-endangerment.

EPA does not agree with commenters who support the use of hydrogeological demonstrations in lieu of wastewater treatment. EPA believes that existing compliance monitoring programs are not sufficient to protect against movement of contaminants into USDWs, nor do they provide sufficient early warning of contamination. To demonstrate that injected fluids are not migrating into and endangering a USDW, a facility would need to show the full areal extent of the fluids' movement and its quality. However, as discussed in the NODA, ground water monitoring wells at most deep well facilities in Florida are only intended to provide some initial indication of fluid movement and are not capable of characterizing the full areal extent of fluid movement, especially where natural conduits for flow are present. Moreover, once any contamination is detected, it may be too late to prevent endangerment.

There are at least two other problems with relying on monitoring for this purpose. First, deep monitoring wells are very costly to site, design, and construct. As stated in the NODA, it is unclear whether it would be practicable to provide a sufficient number of additional ground water monitoring wells to provide the information needed to demonstrate that injection has not caused fluid movement, or that USDWs are not being contaminated at sites where natural conduits for flow exist. Second, there is a potential that monitoring wells installed for this purpose could themselves create artificial conduits for fluid movement. Additional deep monitoring wells would have to perforate all shallow confining layers as they are installed, posing the risk of contamination along the well borehole to more shallow aquifers.

EPA also does not believe that modeling can provide an adequate demonstration in the complex geology of Florida. For example, in the Relative Risk Assessment, EPA used numerical modeling to simulate the time of travel for fluid to move vertically from the injection zone to USDWs and the depth of hypothetical public water supply wells. This modeling used input parameter values for porous media flow (relatively slow movement through small pore spaces) and for preferential flow (rapid movement through larger fissures, cracks, fractures, voids, and channels). The Agency found that the time of travel estimated from the preferential flow model matches actual experience fairly closely at Miami-Dade and Pinellas Counties. However, the modeling only simulated time of travel and did not show the full extent of the movement of injectate from specific sites. A more in-depth modeling effort to show the extent of vertical and horizontal movement of the hundreds of millions of gallons a day would require information on the location and extent of fissures, cracks, voids, and channels which is impossible, using current technologies, to obtain with any certainty. Therefore, the Relative Risk Assessment showed that a credible hydrogeological demonstration that would need to rely on this type of more in-depth modeling does not appear feasible at this time.

Finally, in the public comments, EPA did not receive answers to key questions that it posed in the NODA as to whether hydrogeological demonstrations were feasible (*i.e.*, whether they would work

or whether they were adequate for showing that there was no endangerment to USDWs). Commenters did not describe how the technical challenges and missing information regarding wastewater fate and transport could be overcome, or how the UIC Program Director might address these difficulties in his or her review and decisionmaking. With no new information on how to effectively use monitoring data or effectively simulate the location and extent of channels and solution cavities that are pervasive in Florida's complex geology, a final rule allowing demonstrations would establish an expensive and burdensome approval process. The Agency questions (based on all of the evidence cited above) whether that process would yield credible demonstrations. Before adopting this approach, EPA would need extensive credible evidence that facilities can provide demonstrations that would show where all, or a significant volume, of the fluid is located and that it does not endanger drinking water sources.

Given these uncertainties about the subsurface geology of Florida, the ability of ground water monitoring to identify and characterize the full extent of fluid movement, and the ability of models to predict the movement of fluids in the Florida subsurface, EPA has determined that relying on hydrogeologic demonstrations would not be sufficiently protective of USDWs. Today's rule therefore takes the more conservative approach of requiring owners and operators in certain parts of Florida to treat their injected wastewater using pretreatment, secondary treatment, and high-level disinfection if they wish to avail themselves of the alternative endangerment standard.

C. Monitoring Requirements

Today's rule does not add any new monitoring requirements to those that currently exist in the Federal regulations at 40 CFR 146.13. That section provides the Director with authority to require a site-specific monitoring program and periodic monitoring of ground water quality within the lowermost USDW and aquifer above the injection zone. The State's monitoring requirements and the procedures for modifying those requirements also remain in effect.

In the July 7, 2000, notice, EPA did not propose any changes to the monitoring requirements for Class I municipal disposal wells. EPA did, however, consider adding more specific requirements for effluent and ground water monitoring than currently contained in 40 CFR 146.13, and asked for comments on the appropriate level of monitoring.

EPA agrees with comments on the proposal saying that deep ground-water monitoring does not, by itself, prevent endangerment, and thus is not prescribing new deep monitoring requirements as part of today's rule. EPA believes that the threat of USDW contamination in the targeted areas of Florida is best addressed by requiring the wastewater to be treated with pretreatment, secondary treatment, and high-level disinfection before it is injected. Nevertheless, the Agency recognizes that effluent and ground water monitoring provides an indication of whether treatment is sufficient and working as it was designed and whether fluid movement is occurring. EPA believes that the current authority provided to the Director in 40 CFR 146.13 for a site-specific monitoring program is sufficient and that appropriate monitoring requirements for effluent and ground water will be prescribed by the State in the facility permit. This provision allows the Director to require that certain parameters and contaminants be monitored and reported, some of which have specific health-based limits under the national primary drinking water regulations. The Director also has the authority to require other contaminants to be monitored in order to ''protect the health of persons'' even if a national primary drinking water regulation has not been promulgated.

D. Rule Applicability

1. How Will the New Rule Affect New Wells?

EPA agrees with several public comments on the Agency's proposal, to require any new Class I municipal disposal well constructed in one of the counties in Florida identified in today's rule to meet the pretreatment, secondary treatment, and high-level disinfection standard being established for existing wells. To be clear, the standard applies to any new Class I municipal disposal well in the counties in Florida identified in today's rule, not just new wells at facilities that (as determined and notified by the Director) have caused or may cause fluid movement, per new 40 CFR 146.16 in today's rule.

Contrary to other public comments, EPA does not believe that applying the rule to new wells will prohibit new facilities or wells from being constructed. EPA believes that new wells in the identified counties where there is a history of fluid movement can be constructed and operated to meet the new treatment standards as a way to ensure the protection of USDWs.

2. What Florida Counties Are Covered by the Final Rule?

As mentioned previously, EPA did not receive any public comments regarding the proposed list of Florida counties to be targeted by the rule. Therefore, the rule is being finalized to apply only to publically and privately owned facilities in those counties listed in the proposal, as follows: Brevard, Broward, Charlotte, Collier, Flagler, Glades, Hendry, Highlands, Hillsborough, Indian River, Lee, Manatee, Martin, Miami-Dade, Monroe, Okeechobee, Orange, Osceola, Palm Beach, Pinellas, St. Johns, St. Lucie, Sarasota, and Volusia. These counties are being targeted because they have the unique geologic conditions that are predominated by carbonate rocks, as discussed above.

E. Reclassification of Wells That Have Caused Fluid Movement

In today's action, EPA is promulgating new Class I requirements. In the NODA, EPA asked for comment on whether, based on the findings of the Relative Risk Assessment, wells with fluid movement should be regulated as Class I, Class V, or under provisions for both Class I and Class V.

Public comments on this issue were mixed. Some commenters were in favor of reclassifying the wells as Class V, saying that the injection zone and confining layers are sufficiently similar to be considered a single formation. Other commenters were against reclassifying the wells as Class V, citing concerns that doing so would lead to greater reliance on injection as a wastewater disposal method or that Class V standards would provide less protection.

After considering these different approaches and public comments, EPA believes the best approach is to keep the wells as Class I and impose the new requirements as a condition for future injection. As previously discussed in Section IV A, this approach does represent a change in the criteria (i.e., currently ''no fluid movement'') that apply to certain Class I wells in certain counties in Florida, but it embraces the long-standing approach of controlling injectate quality as a way to ensure protection when fluid movement is known or suspected. Therefore, EPA believes that the rule is protective and entirely consistent with measures used in the Federal UIC Program, does not undermine the goals or integrity of the Class I program, and does not set a dangerous precedent for other Class I

EXHIBIT 12

wells found to be causing fluid movement. Reclassifying the wells as Class V would provide no greater protection than this rule but would introduce substantial confusion and new burdens to well owners and operators and regulators, who would have to develop and implement substantially revised UIC programs.

V. Cost of the Rule

In the absence of the availability of the regulatory alternative in today's rule, owners and operators with wells that have caused or may cause fluid movement to a USDW would need to find a way to operate so that the injected fluid does not move into a USDW. However, that simply cannot be done if the movement is a function of a lack of sufficient confinement. Owners and operators would face having to close their wells and adopt other disposal alternatives. For the purpose of estimating the cost of the final rule, EPA assumes that operators would have to use surface disposal, because Florida has not approved new ocean disposal pipelines for many years in order to protect its coral reefs and beaches.

The economic analysis supporting today's rule compares the costs of compliance under the previous regulations (the baseline) with the costs of compliance under the new rule. The baseline scenario assumes that operators of affected wells would be required to abandon their injection wells and switch to surface disposal. Assumptions for estimating the cost of complying with today's rule include the addition of treatment necessary at each affected facility to meet the high-level disinfection requirements of Florida Rule 62–600.440(5)(a)–(f). Of a total of 42 Class I municipal disposal well facilities in Florida, EPA estimates that approximately 16 cause or may cause fluid movement into a USDW and therefore fall within the scope of this rule. EPA estimates costs only for those 16 facilities.

To develop the cost estimates, EPA used Version 3.0 of EPA's W/W Costs Model, combined with a methodology recommended by the National Drinking Water Advisory Council (NDWAC). The W/W Costs Model generates capital and annual operations and maintenance (O&M) costs based on treatment technology, design and average daily flows, and chemical dose.

EPA relied on information from Florida DEP to determine the number of wells that would likely be affected by the rule. The State reports that there has been confirmed fluid movement into USDWs from deep wells at three facilities. The State also reports that fluid has likely moved into USDWs from wells at another five facilities and that fluid has moved outside of the permitted injection zone into a non-USDW at another eight facilities.

EPA also used relevant information from domestic wastewater facility permits, compliance monitoring data, and information about the availability of high-level disinfection to determine the required treatment upgrades for each facility. At many of these facilities, high-level disinfection capacity is already in place; at the remainder, if movement into the USDW is likely, high-level disinfection will be necessary if the well is to avail itself of the authorization to inject provided by this rule, once these requirements are adopted by Florida as part of its UIC program and approved by EPA. For this reason, EPA has included all 16 of the wells with varying degrees of fluid movement or suspected movement in the economic assessment for the rule. The 16 facilities included in the cost assessment are for the purpose of estimating the cost of today's rule. This rule does not specifically require any of these facilities to install additional treatment. The remaining wells in Florida with no fluid movement outside the injection zone may never have fluid movement detected in deep monitoring wells, or, over a period of years and decades, some will show fluid movement. Due to this level of uncertainty, EPA did not include them in the economic assessment for this rule. EPA does not believe that owners and operators will incur additional costs due to the pretreatment requirements of this rule, because the 16 facilities with varying degrees of fluid movement or suspected movement already have a pretreatment plan in place or have no significant industrial users.

Based on the cost analysis, today's rule is significantly less costly than the baseline requirements. The table below presents a summary of the total capital and annualized costs (at two discount rate scenarios—3 percent and 7 percent) for the baseline case and under today's rule. The cost savings are calculated by subtracting costs for the injection requirements associated with today's alternative approach from the baseline case. As the table shows, the costs for meeting the new requirements for 14 of 16 existing facilities, that are not already required to install additional wastewater treatment, where there is some form of fluid movement or suspected movement is $27.7 million in capital costs and $7.2 million annually (3 percent discount rate), including O&M, as compared to the baseline costs of $132.2 million in capital costs and $15.2 million annually (3 percent discount rate). At the 7 percent discount rate, the annualized capital costs and O&M costs are $7.9 million. Thus, today's alternative represents a savings of $104.5 million in capital costs and $8.0 million annually at the 3 percent discount rate ($12.6 million at the 7 percent discount rate). EPA's complete cost estimation document is in the Florida UIC docket.

Scenario	Total cost (in millions)			Average cost per facility—based on 14 facilities * (in millions)		
	Capital costs	Annualized costs (annualized capital + O&M)		Capital costs	Annualized costs (annualized capital + O&M)	
		3%	7%		3%	7%
Baseline: Abandon injection wells and switch to surface disposal	$132.2	$15.2	$20.6	$9.4	$1.1	$1.5
Today's rule: Continue injecting after treating with high-level disinfection	27.7	7.2	7.9	2.0	0.5	0.6
Cost Savings	104.5	8.0	12.6	7.5	0.6	0.9

Note: Numbers may not appear to add due to independent rounding.
Costs are annualized over 20 years.
* Two of the 16 affected facilities are under a consent order and are excluded from the cost analysis.

EPA solicited comments on the cost estimation approach. A few commenters provided input on costs at specific affected facilities, and several general comments were offered on the cost analysis, including that it is overly simplistic, given the complexity of the rule. Many commenters believed the cost of the rule as proposed was too high. The comment response documents in the Florida UIC docket provide a more complete summary of and response to these comments on the cost analysis.

VI. Statutory and Executive Order Reviews

A. 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.

It has been determined that this rule is not a ''significant regulatory action'' under the terms of Executive Order 12866 and is therefore not subject to OMB review.

One comment was submitted on this topic, stating that the proposed rule is a significant regulatory action. The commenter believes the rule will create a serious inconsistency or otherwise interfere with an action by another agency and will raise novel legal and policy issues. The commenter did not provide any specific information in support of the comment. EPA does not agree with this comment. Providing this alternative set of requirements for certain Class I wells in Florida does not create any inconsistency with the rest of the UIC program, nor does it raise novel issues triggering this Executive Order. Today's alternative applies the Agency's long-standing Class V endangerment test to a class of municipal disposal wells that are unique to Florida. That these wells are suspected of injecting below formations without adequate confinement makes application of the Class V standard both reasonable and appropriate. As noted in Section V above, the Agency estimates that implementing the selected option will result in a savings of $104.5 million in capital costs and $8.0 million annually.

B. Paperwork Reduction Act

The information collection requirements in this rule have been submitted for approval to Office of Management and Budget (OMB) under the Paperwork Reduction Act, 44 U.S.C. 3501 *et seq.* The information collection requirements are not enforceable until OMB approves them.

The ICR estimates monitoring, demonstration, reporting, and recordkeeping burdens and costs for Class I municipal disposal well operators in selected parts of Florida associated with today's rule. Class I municipal disposal well operators must submit this information per § 144.51 of the CFR. Information regarding wastewater quality, treatment, and migration will be collected as outlined in the rule for review by the State of Florida as primacy agent. Under the rule, the Primacy State would be required to revise and resubmit a UIC program application for Class I wells.

Information collected under SDWA and, by extension, this ICR is expected to be used by EPA and the State of Florida to help ensure the maintenance of clean, safe public drinking water supplies.

Operators of injection wells may claim confidentiality, as provided in section 144.5, Confidentiality of Information. If confidentiality is requested, the information is treated in accordance with the provisions of 40 CFR part 2, Public Information. Information collected under this ICR is intended for the Agency's and/or State's internal use and there are no plans to routinely release or publish any of the data. However, if no claim of confidentiality is made at the time of submission, the information can be made available to the public without further notice.

EPA estimates that the average annual burden on Class I municipal disposal well operators (which includes public and private entities) and the State of Florida associated with this rule will be 2,003 hours. This is based on an estimate that one State, Florida, will need to provide 6 responses each year at 88.4 hours per response. It is also estimated that each of the 16 Class I municipal disposal well operators will need to provide an average of 10.7 responses each year at an average of 138 hours per response. The labor burden is estimated for activities associated with reading and understanding the rule, performing and reviewing monitoring, and meeting primacy requirements. No respondents are expected to incur capital or O&M costs to complete information collection requirements. Burden means the total time, effort, or financial resources expended by persons to generate, maintain, retain, or disclose or provide information to or for a Federal agency. This includes the time needed to review instructions; develop, acquire, install, and utilize technology and systems for the purposes of collecting, validating, and verifying information, processing and maintaining information, and disclosing and providing information; adjust the existing ways to comply with any previously applicable instructions and requirements; train personnel to be able to respond to a collection of information; search data sources; complete and review the collection of information; and transmit or otherwise disclose the information.

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

C. Regulatory Flexibility Act

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

For purposes of assessing the impacts of today's action on small entities, a small entity is defined as: (1) A small business that is primarily engaged in waste management services as defined by NAICS code 562998 with annual revenue less than $6 million according

to Small Business Administration size standards; (2) a small governmental jurisdiction that is a government of a city, county, town, school district or special district with a population of less than 50,000; and (3) a small organization that is any not-for-profit enterprise which is independently owned and operated and is not dominant in its field.

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 determining whether a rule has significant economic impact on a substantial number of small entities, the impact of concern is any significant adverse economic impact on small entities, since the primary purpose of the regulatory flexibility analyses is to identify and address regulatory alternatives ''which minimize any significant economic impact of the rule on small entities.'' 5 U.S.C. 603 and 604. Thus, an agency may certify that a rule will not have a significant economic impact on a substantial number of small entities if the rule relieves regulatory burden, or otherwise has a positive economic effect on all of the small entities subject to the rule.

Of a total of 42 Class I municipal disposal well facilities in Florida, EPA estimates that approximately 16 cause or may cause fluid movement into a USDW and fall within the scope of this rule. As discussed in Section V, the economic impact of this action actually results in a cost savings to the Class I municipal disposal well facilities compared to the baseline, i.e., complying with existing UIC regulations. Because Class I municipal disposal well facilities that may avail themselves of the authorization to inject provided by this rule are only affected if they cause or may cause fluid movement prohibited by present law, EPA has determined that the effect on small entities will be positive to the extent they are impacted. If the entity chooses not to follow these new requirements, the legal status of its continued operations is not impacted by the rule. We have therefore concluded that today's final rule either will have no effect on or, in the alternative, will relieve regulatory burden for all small entities.

D. Unfunded Mandates Reform Act

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 section 202 of the UMRA, EPA generally must prepare a written statement, including a cost-benefit analysis, for proposed and final rules with ''Federal mandates'' that may result in expenditures to State, local, and Tribal governments, in the aggregate, or to the private sector, of $100 million or more in any one year. Before promulgating an EPA rule for which a written statement is needed, section 205 of the UMRA generally requires EPA to identify and consider a reasonable number of regulatory alternatives and adopt the least costly, most cost-effective or least burdensome alternative that achieves the objectives of the rule. The provisions of section 205 do not apply when they are inconsistent with applicable law. Moreover, section 205 allows EPA to adopt an alternative other than the least costly, most cost-effective or least burdensome alternative if the Administrator publishes with the final rule an explanation why that alternative was not adopted. Before EPA establishes any regulatory requirements that may significantly or uniquely affect small governments, including Tribal governments, it must have developed under Section 203 of the UMRA a small government agency plan. The plan must provide for notifying potentially affected small governments, enabling officials of affected small governments to have meaningful and timely input in the development of EPA regulatory proposals with significant Federal intergovernmental mandates, and informing, educating, and advising small governments on compliance with the regulatory requirements.

Today's rule contains no Federal mandate (under the provisions of Title II of the UMRA) for State, local, and Tribal governments or the private sector. Because the authorization to inject provided for by today's rule is optional on applicants, the costs incurred by an entity in conjunction with such authorization to inject under the rule are discretionary, not mandated. The total cost impact, in comparison to other alternatives to provide effective wastewater disposal, is anticipated to be positive for those entities that choose to avail themselves of the option provided by this rule. This rule will reduce the burden imposed by the current regulations. 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. This rule is not targeted at small governments. It offers owners and operators of Class I municipal disposal wells in certain parts of Florida that inject domestic wastewater effluent an alternative method of compliance with the existing UIC rules, which prohibit fluid movement, without requiring the facilities to cease injection and abandon their existing Class I municipal disposal wells. This rule will provide them with a less burdensome alternative for compliance. Thus, today's rule is not subject to the requirements of section 203 of the UMRA.

E. Executive Order 13132: Federalism

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

This 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. The rule allows for an optional alternate method for the State of Florida to use to ensure that no owner and/or operator would endanger a USDW by injection of domestic wastewater effluent into a Class I municipal disposal well. EPA is not requiring that an owner and/or operator use this authorization, but rather is providing options that owners and/or operators of existing Class I municipal disposal wells may wish to use in order to maintain their injection operations. Thus, the requirements of Section 6 of the Executive Order do not apply to this rule. Although Section 6 of Executive Order 13132 does not apply to this rule, EPA did consult with the Florida Department of Environmental Protection (FDEP) in developing this rule and FDEP agrees with EPA's approach.

Two public comments were submitted on this topic. Both comments suggest EPA should revise its determination under Executive Order 13132, and claim the rule imposes significant burdens and costly solutions on the State of Florida. One commenter suggested that EPA modify its final rule to allocate all permitting decisions solely to the State.

In response, today's rule does not change the current process by which the State of Florida exercises its primacy over injection operations in the State. While the State would have to revise and resubmit a UIC program application for Class I wells if it wished to provide owners and operators of Class I municipal disposal wells in Florida with the optional authorization contained in this rule, it is anticipated that the Director will retain authority over Class I injection in Florida. In the spirit of Executive Order 13132, and consistent with EPA policy to promote communications between EPA and State and local governments, EPA solicited comment on the proposed rule from State officials.

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

Executive Order 13175, entitled ''Consultation and Coordination with Indian Tribal Governments'' (65 FR 67249, November 9, 2000), requires EPA to develop an accountable process to ensure ''meaningful and timely input by Tribal officials in the development of regulatory policies that have Tribal implications.''

This final rule does not have Tribal implications as specified in Executive Order 13175. At present, there are no Class I injection wells used for domestic wastewater effluent disposal in Florida that are owned or operated by an Indian Tribal community. The intent of this rule is to protect all USDWs from endangerment caused by Class I municipal disposal wells, including those on Tribal land.

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

Executive Order 13045: ''Protection of Children from Environmental Health 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.

This final rule is not subject to Executive Order 13045 because it is not economically significant as defined in Executive Order 12866, and because the Agency does not have reason to believe the environmental health or safety risks addressed by this action present a disproportionate risk to children. The rule provides an optional authorization for certain Class I wells in Florida to inject domestic wastewater effluent in accordance with regulatory requirements designed to prevent endangerment of underground sources of drinking water. The criteria established in the rule safeguard these resources for all potential users, including but not limited to children.

Three comments were received on this topic from environmental advocates and a citizen. All three suggest that the proposal has not adequately assessed potential risk to children's health, or that contaminants in injected wastewater may have a disproportionate effect on vulnerable populations, including children. EPA disagrees that Class I municipal disposal of wastewater that has been subjected to pretreatment, secondary treatment, and high-level disinfection as a result of this rule will have a disproportionate impact on children or any other vulnerable population. By requiring pretreatment, secondary treatment, and high-level disinfection as a condition of future operation of the targeted injection wells, the rule is ensuring the protection of USDWs and the health of children who may rely on these USDWs as drinking water sources.

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

This rule is not subject to Executive Order 13211, ''Actions That Significantly Affect Energy Supply, Distribution, or Use'' (66 FR 28355 (May 22, 2001)) because it is not a significant regulatory action under Executive Order 12866.

I. National Technology Transfer and Advancement Act

As noted in the proposed rule, section 12(d) of the National Technology Transfer and Advancement Act of 1995 (''NTTAA''), Public Law. No. 104–113, 12(d), (15 U.S.C. 272 note) directs EPA to use voluntary consensus standards in its regulatory activities unless to do so would be inconsistent with applicable law or otherwise impractical. Voluntary consensus standards are [Underground Injection Control Program—Revision of Federal Underground Injection Control Requirements for Class I Municipal Disposal Wells in Florida Page 62 of 62.] technical standards (e.g., materials specifications, test methods, sampling procedures, and business practices) that are developed or adopted by voluntary consensus standards bodies. The NTTAA directs EPA to provide Congress, through OMB, explanations when the Agency decides not to use available and applicable voluntary consensus standards. This action does not involve technical standards. Therefore, EPA does not consider the use of any voluntary consensus standards.

J. 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 on December 22, 2005.

List of Subjects in 40 CFR Part 146

Environmental protection, Hazardous waste, Indians-lands, Water supply.

Dated: November 15, 2005.

Stephen L. Johnson,

Administrator.

■ For the reasons set forth in the preamble, 40 CFR part 146 is amended as follows:

PART 146—UNDERGROUND INJECTION CONTROL PROGRAM: CRITERIA AND STANDARDS

■ 1. The authority citation for part 146 continues to read as follows:

Authority: Safe Drinking Water Act, 42 U.S.C. 300f et seq.; Resource Conservation and Recovery Act, 42 U.S.C. 6901 et seq.

Subpart B—Criteria and Standards Applicable to Class I Wells

■ 2. Section 146.15 is added to Subpart B to read as follows:

§ 146.15 Class I municipal disposal well alternative authorization in certain parts of Florida.

(a) Existing Class I municipal disposal wells in specific geographic regions as defined in paragraph (f) of this section may continue to inject without violating the regulatory prohibitions in Parts 144 and 146 of this chapter against the

EXHIBIT 12

movement of injection or formation fluids into a USDW, provided that such wells meet the requirements of this section, even if the Director determines they have caused or may cause fluid movement into a USDW. Nothing in this section excuses such Class I municipal disposal wells from meeting all other applicable State and Federal requirements including 40 CFR 144.12(a).

(b) For purposes of this section, an existing Class I municipal disposal well is defined as a well for which a complete UIC construction permit application was received by the Director on or before December 22, 2005.

(c) For purposes of this section, the determination that a Class I municipal disposal well has caused or may cause movement of injection or formation fluids into a USDW may be made by the Director based on any relevant data available to him/her, including ground water monitoring data generated pursuant to regulatory requirements governing operation of Class I municipal disposal wells.

(d) In order for a Class I municipal disposal well to qualify for authorization to inject pursuant to paragraph (a) of this section, the Owner/Operator of that well shall:

(1) Develop and implement a pretreatment program that is no less stringent than the requirements of Chapter 62–625, Florida Administrative Code, or have no significant industrial users as defined in that chapter.

(2) Treat the injectate using secondary treatment in a manner that is no less stringent than the requirements of Florida Rule 62–600.420(1)(d), and using high-level disinfection in a manner that is no less stringent than the requirements of Florida Rule 62–600.440(5)(a)–(f), within five years after notification by the Director that the well has caused or may cause fluid movement into a USDW.

(e) Where the Director issued such notice for a well prior to December 22, 2005, in order for that well to qualify for authorization to inject pursuant to paragraph (a) of this section, the Owner/Operator shall:

(1) Develop and implement a pretreatment program that is no less stringent than the requirements of Chapter 62–625, Florida Administrative Code, or have no significant industrial users as defined in that chapter; and

(2) Treat the injectate using secondary treatment in a manner that is no less stringent than the requirements of Florida Rule 62–600.420(1)(d), and using high-level disinfection in a manner that is no less stringent than the requirements of Florida Rule 62–600.440(5)(a)–(f), within five years after December 22, 2005.

(f) Authorization to inject wastewater into existing Class I municipal disposal wells pursuant to this section is limited to Class I municipal disposal wells in Florida in the following counties: Brevard, Broward, Charlotte, Collier, Flagler, Glades, Hendry, Highlands, Hillsborough, Indian River, Lee, Manatee, Martin, Miami-Dade, Monroe, Okeechobee, Orange, Osceola, Palm Beach, Pinellas, St. Johns, St. Lucie, Sarasota, and Volusia.

■ 3. Section 146.16 is added to Subpart B to read as follows:

§ 146.16 Requirements for new Class I municipal wells in certain parts of Florida.

Prior to commencing injection, any Class I municipal disposal well in one of the counties identified in § 146.15(f) that is not an existing Class I municipal disposal well as defined in § 146.15(b) of this section shall meet all of the requirements for existing wells seeking authorization to inject pursuant to § 146.15.

[FR Doc. 05–23088 Filed 11–21–05; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Part 418

[CMS–1022–F]

RIN 0938–AJ36

Medicare Program; Hospice Care Amendments

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Final rule.

SUMMARY: This final rule revises existing regulations that govern coverage and payment for hospice care under the Medicare program. These revisions reflect the statutory changes required by the Balanced Budget Act of 1997 (BBA), the Medicare, Medicaid, and SCHIP Balanced Budget Refinement Act of 1999 (BBRA), and the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (BIPA). Additionally, these revisions reflect current policy on the documentation needed to support a certification of terminal illness, admission to Medicare hospice, and a new requirement that allows for discharges from hospice for cause under very limited circumstances.

This final rule does not address the requirement for hospice data collection, the changes to the limitation of liability rules, or the changes to the hospice conditions of participation that were included in the BBA.

The intent of this final rule is to expand the hospice benefit periods, improve documentation requirements to support certification and recertification of terminal illness, provide guidance on hospice admission procedures, clarify hospice discharge procedures, update coverage and payment requirements, and address the changing needs of beneficiaries, suppliers, and the Medicare program.

DATES: These regulations are effective on January 23, 2006.

FOR FURTHER INFORMATION CONTACT: Linda Smith, (410) 786–5650.

SUPPLEMENTARY INFORMATION:

I. Background

A. Hospice Care

Hospice care means a comprehensive set of services described in 1861(dd)(1) of the Social Security Act (the Act), identified and coordinated by an interdisciplinary team to provide the physical, psychosocial, spiritual, and emotional needs of a terminally ill patient and family members or both as denoted in a specific patient plan of care.

The emphasis of hospice care is on the control of pain and the furnishing of services that enable the beneficiary to remain at home as long as possible with minimal disruption to normal activities. A hospice uses an interdisciplinary approach to deliver medical, social, psychological, emotional, and spiritual services through the use of a broad spectrum of professional and other caregivers, with the goal of making the individual as physically and emotionally comfortable as possible. Counseling and respite services are available to the family of the hospice patient. Hospice programs consider both the patient and the family as the unit of care.

B. Medicare Hospice Before the Balanced Budget Act of 1997

The Balanced Budget Act of 1997 changed and clarified numerous aspects of the Medicare hospice benefit including the length of available benefit periods, the amount of annual updates, how local payment rates are determined, the time frame for physician certification, and what is considered a covered Medicare hospice service. Section 1861(dd) of the Act provides for coverage of hospice care for terminally ill Medicare beneficiaries