

IV. Statutory and Executive Order Reviews

Under the Clean Air Act, the Administrator is required to approve a SIP submission that complies with the provisions of the Act and applicable Federal regulations. 42 U.S.C. 7410(k); 40 CFR 52.02(a). Thus, in reviewing SIP submissions, EPA's role is to approve State choices, provided that they meet the criteria of the Clean Air Act. Accordingly, this action merely approves State law as meeting Federal requirements and does not impose additional requirements beyond those imposed by State law. For that reason, this action:

- Is not a "significant regulatory action" subject to review by the Office of Management and Budget under Executive Order 12866 (58 FR 51735, October 4, 1993);
- Does not impose an information collection burden under the provisions of the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*);
- Is certified as not having a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*);
- Does not contain any unfunded mandate or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Pub. L. 104-4);
- Does not have Federalism implications as specified in Executive Order 13132 (64 FR 43255, August 10, 1999);
- Is not an economically significant regulatory action based on health or safety risks subject to Executive Order 13045 (62 FR 19885, April 23, 1997);
- Is not a significant regulatory action subject to Executive Order 13211 (66 FR 28355, May 22, 2001);
- Is not subject to requirements of Section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) because application of those requirements would be inconsistent with the Clean Air Act; and
- Does not provide EPA with the discretionary authority to address, as appropriate, disproportionate human health or environmental effects, using practicable and legally permissible methods, under Executive Order 12898 (59 FR 7629, February 16, 1994).

In addition, this rule does not have tribal implications as specified by Executive Order 13175 (65 FR 67249, November 9, 2000), because the SIP is not approved to apply in Indian country located in the State, and EPA notes that it will not impose substantial direct

costs on tribal governments or preempt tribal law.

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 action 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).

Under section 307(b)(1) of the Clean Air Act, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by January 11, 2010. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this action for the purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action. This action may not be challenged later in proceedings to enforce its requirements (see section 307(b)(2)).

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Incorporation by reference, Intergovernmental relations, Particulate matter, Reporting and recordkeeping requirements.

Dated: September 18, 2009.

Jane Diamond,

Acting Regional Administrator, Region IX.

■ Part 52, Chapter I, Title 40 of the Code of Federal Regulations is amended as follows:

PART 52—[AMENDED]

■ 1. The authority citation for Part 52 continues to read as follows:

Authority: 42 U.S.C. 7401 *et seq.*

Subpart F—California

■ 2. Section 52.220 is amended by adding paragraphs (c)(364)(i)(A)(2) and (c)(364)(i)(B), and (c)(366) to read as follows:

§ 52.220 Identification of plan.

- * * * * *
- (c) * * *
- (364) * * *

- (i) * * *
- (A) * * *

(2) Rule 4901, "Wood Burning Fireplaces and Wood Burning Heaters," amended on October 16, 2008.

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(B) South Coast Air Quality Management District.

(1) Rule 1158, "Storage, Handling, and Transport of Coke, Coal and Sulfur," amended July 11, 2008.

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(366) New and amended regulations for the following agencies were submitted on April 6, 2009, by the Governor's designee.

(i) *Incorporation by reference.*

(A) San Joaquin Valley Unified Air Pollution Control District.

(1) Rule 4103, "Open Burning," amended May 17, 2007.

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 141

[EPA-HQ-OW-2009-0707; FRL-8979-5]

Expedited Approval of Alternative Test Procedures for the Analysis of Contaminants Under the Safe Drinking Water Act; Analysis and Sampling Procedures

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This action announces the Environmental Protection Agency's (EPA's) approval of alternative testing methods for use in measuring the levels of contaminants in drinking water and determining compliance with national primary drinking water regulations. The Safe Drinking Water Act (SDWA) authorizes EPA to approve the use of alternative testing methods through publication in the **Federal Register**. EPA is using this streamlined authority to make 25 additional methods available for analyzing drinking water samples required by regulation. This expedited approach provides public water systems, laboratories, and primacy agencies with more timely access to new measurement techniques and greater flexibility in the selection of analytical methods, thereby reducing monitoring costs while maintaining public health protection.

DATES: This action is effective November 10, 2009.

FOR FURTHER INFORMATION CONTACT: Safe Drinking Water Hotline: (800) 426-4791

or Patricia Snyder Fair, Technical Support Center, Office of Ground Water and Drinking Water (MS 140), Environmental Protection Agency, 26 West Martin Luther King Drive, Cincinnati, OH 45268; telephone number: (513) 569-7937; e-mail address: fair.pat@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does This Action Apply to Me?

Public water systems are the regulated entities required to measure

contaminants in drinking water samples. In addition, EPA Regions as well as States and Tribal governments with authority to administer the regulatory program for public water systems under SDWA may also measure contaminants in water samples. When EPA sets a monitoring requirement in its national primary drinking water regulations for a given contaminant, the Agency also establishes in the regulations standardized test procedures for analysis of the contaminant. This action makes alternative testing

methods available for particular drinking water contaminants beyond the testing methods currently established in the regulations. EPA is providing public water systems required to test water samples with a choice of using either a test procedure already established in the existing regulations or an alternative test procedure that has been approved in this action. Categories and entities that may ultimately be affected by this action include:

| Category | Examples of potentially regulated entities | NAICS ¹ |
|--|--|--------------------|
| State, Local, & Tribal Governments | States, local and Tribal governments that analyze water samples on behalf of public water systems required to conduct such analysis; States, local and Tribal governments that themselves operate community and non-transient non-community water systems required to monitor. | 924110 |
| Industry | Private operators of community and non-transient non-community water systems required to monitor. | 221310 |
| Municipalities | Municipal operators of community and non-transient non-community water systems required to monitor. | 924110 |

¹ North American Industry Classification System.

This table is not exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this action. This table lists the types of entities that EPA is now aware could potentially be affected by this action. Other types of entities not listed in the table could also be impacted. To determine whether your facility is affected by this action, you should carefully examine the applicability language at 40 CFR 141.2 (definition of public water system). If you have questions regarding the applicability of this action to a particular entity, consult the person listed in the preceding **FOR FURTHER INFORMATION CONTACT** section.

B. How Can I Get Copies of This Document and Other Related Information?

Docket. EPA established a docket for this action under Docket ID No. EPA-HQ-OW-2009-0707. Publicly available docket materials are available either electronically through <http://www.regulations.gov> or in hard copy at the Water Docket in the EPA Docket Center, (EPA/DC) EPA West, Room 3334, 1301 Constitution Ave., NW., Washington, DC. Copyrighted materials are available only in hard copy. The EPA Docket Center Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566-1744, and the telephone number for the Water Docket is (202) 566-2426.

Abbreviations and Acronyms Used in This Action

- CFR: Code of Federal Regulations.
- DOC: Dissolved Organic Carbon.
- DPD: N,N-Diethyl-p-phenylenediamine.
- E. coli*: *Escherichia coli*.
- EPA: Environmental Protection Agency.
- HAA5: Haloacetic Acids (five); Sum of Monochloroacetic Acid, Dichloroacetic Acid, Trichloroacetic Acid, Monobromoacetic Acid, and Dibromoacetic Acid.
- IC: Ion Chromatography.
- IC-ESI-MS/MS: Ion Chromatography Electropray Ionization Tandem Mass Spectrometry.
- LED: Light Emitting Diode.
- mg/L: Milligrams/Liter.
- MRL: Minimum Reporting Level.
- NEMI: National Environmental Methods Index.
- nm: Nanometers.
- QC: Quality Control.
- SDWA: Safe Drinking Water Act.
- SUVA: Specific Ultraviolet Absorbance.
- TOC: Total Organic Carbon.
- UV₂₅₄: Ultraviolet Absorbance at 254 nanometers.

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II. Background

A. What Is the Purpose of This Action?

In this action, EPA is approving 25 analytical methods for determining contaminant concentrations in samples collected under SDWA. Regulated parties required to sample and monitor may use either the testing methods already established in existing regulations or the alternative testing methods being approved in this action. The new methods are listed in Appendix A to Subpart C in 40 CFR 141 and on EPA's drinking water methods Web site at http://www.epa.gov/safewater/methods/analyticalmethods_expedited.html.

B. What Is the Basis for This Action?

When EPA determines that an alternative analytical method is "equally effective" (*i.e.*, as effective as a method that has already been promulgated in the regulations), SDWA allows EPA to approve the use of the alternative method through publication in the **Federal Register**. (See Section 1401(1) of SDWA.) EPA is using this streamlined approval authority to make 25 additional methods available for determining contaminant concentrations in samples collected under SDWA. EPA has determined that, for each contaminant or group of contaminants listed in Section III, the additional testing methods being approved in this action are equally effective as one or more of the testing methods already established in the regulations for those contaminants.

Section 1401(1) states that the newly approved methods “shall be treated as an alternative for public water systems to the quality control and testing procedures listed in the regulation.” Accordingly, this action makes these additional (and optional) 25 analytical methods legally available for meeting EPA’s monitoring requirements.

This action does not add regulatory language, but does, for informational purposes, update an appendix to the regulations at 40 CFR part 141 that lists all methods approved under Section 1401(1) of SDWA. Accordingly, while this action is not a rule, it is updating CFR text and therefore is being published in the “Final Rules” section of this **Federal Register**.

EPA described this expedited methods approval process in an April 10, 2007, **Federal Register** notice (72 FR 17902) (USEPA 2007) and announced its intent to begin using the process. EPA published the first set of approvals in a June 3, 2008, **Federal Register** notice (73 FR 31616) (USEPA 2008) and added Appendix A to 40 CFR Part 141, Subpart C. Six additional methods were added to Appendix A to Subpart C in an August 3, 2009, **Federal Register** notice (74 FR 38348) (USEPA 2009a). Future approvals using this process are anticipated.

III. Summary of Approvals

EPA is approving 25 methods that are equally effective relative to methods previously promulgated in the regulations. By means of this notice, these 25 methods are added to Appendix A of 40 CFR Part 141, Subpart C.

A. Methods Developed by EPA

1. EPA Method 334.0, “Determination of Residual Chlorine in Drinking Water Using an On-line Chlorine Analyzer” (USEPA 2009b) establishes quality control (QC) criteria for on-line chlorine analyzers such that the analyzers provide data equivalent to the grab sample methodologies that are already approved in the regulations. The on-line chlorine analyzer is calibrated using aqueous standards or the results from grab samples that are collected at the same sample point as used by the analyzer. The grab samples are analyzed for chlorine using a method that is approved for drinking water compliance monitoring. The accuracy of the on-line chlorine analyzer is periodically verified (and adjustments made when necessary) based on results from grab sample analyses.

Previously approved methods for determining free and total chlorine residuals in drinking water are listed in

the tables at 40 CFR 141.74(a)(2) and 40 CFR 141.131(c)(1). All of the methods are designed for grab sample analyses. The regulation at 40 CFR 141.74(a)(2) also states, “Free and total chlorine residuals may be measured continuously by adapting a specified chlorine residual method for use with a continuous monitoring instrument provided the chemistry, accuracy, and precision remain the same. Instruments used for continuous monitoring must be calibrated with a grab sample measurement at least every five days, or with a protocol approved by the State.”

Continuous monitoring instruments that use N,N-Diethyl-p-phenylenediamine (DPD) chemistry are the only on-line chlorine analyzers that, prior to this action, met the drinking water regulatory requirement to use the same chemistry as an approved method. The instruments perform chlorine residual measurements on a frequent basis using an automated version of Standard Method 4500–Cl G (APHA 1998), which is listed in the tables at 40 CFR 141.74(a)(2) and 40 CFR 141.131(c)(1). Since the instruments use an approved method, they have the capability to provide the same accuracy and precision as the approved method (Standard Method 4500–Cl G), if they are properly installed and maintained. The performance characteristics of the instruments are periodically checked by comparing the instrumental results to grab sample measurements according to a protocol approved by the State.

EPA Method 334.0 now allows the use of on-line chlorine analyzers based on chemistry different from that of approved methods. It is a “performance based” method, which means it establishes QC criteria to bench-mark the performance of the on-line chlorine analyzer against the performance of approved grab sample methods. As long as the on-line analyzer meets the QC criteria in EPA Method 334.0, the data are deemed equivalent to data obtained using the approved grab sample methods. EPA Method 334.0 can be used with any type of on-line chlorine analyzer.

Data from 38 drinking water treatment facilities (EE&T, Inc. 2009) were used as the basis for establishing the on-line chlorine analyzer QC criteria in EPA Method 334.0. Chlorine residual measurements from on-line amperometric chlorine analyzers were compared to the results from grab sample analyses performed using either Standard Method 4500–Cl D (amperometric titration) (APHA 1998) or Standard Method 4500–Cl G (DPD colorimetric). Both Standard Methods are approved for drinking water

compliance monitoring analyses and are listed in the tables at 40 CFR 141.74(a)(2) and 40 CFR 141.131(c)(1). The data from the 38 facilities demonstrate that on-line amperometric chlorine analyzers can provide data that are equivalent to approved methods.

EPA Method 334.0 requires that the analyst demonstrate that the grab sample method provides reliable data prior to using it to verify the performance of an on-line chlorine analyzer. This QC requirement is consistent with the QC requirements in the approved grab sample methods. Aqueous standards are analyzed to demonstrate the accuracy and precision of the measurements. EPA recommends that the grab sample QC requirements in EPA Method 334.0 be used with all on-line chlorine analyzers, including those that are originally approved under the provisions of 40 CFR 141.74.

A preliminary draft of EPA Method 334.0 was provided to the Association of State Drinking Water Administrators, the American Water Works Association, and the Water and Wastewater Equipment Manufacturers Association. A revised draft was reviewed by persons from two State agencies and two drinking water utilities. The final method reflects changes made in response to review comments. The public docket for this action includes the comments from these organizations and the Agency’s response to comments (USEPA 2009c).

EPA has determined that EPA Method 334.0 is equally effective for measuring free and total chlorine residuals as the methods that are promulgated in the regulations at 40 CFR 141.74(a)(2) and 40 CFR 141.131(c)(1). The basis for this determination is discussed in Fair and Wendelken 2009. EPA is therefore approving use of EPA Method 334.0 for on-line analyses of free and total chlorine. A copy of the method can be accessed and downloaded directly on-line at http://epa.gov/safewater/methods/analyticalmethods_ogwdw.html.

2. EPA Method 302.0, “Determination of Bromate in Drinking Waters using Two-Dimensional Ion Chromatography with Suppressed Conductivity Detection” (USEPA 2009d) is a large volume (1.0 mL), two-dimensional ion chromatography (IC) method that uses suppressed conductivity detection for the determination of bromate in raw and finished drinking waters. Because this method utilizes two dissimilar IC columns it does not require second column confirmation. Detection and quantitation are accomplished in the second dimension by suppressed conductivity measurement. Bromate

concentration is calculated using the integrated peak area and the external standard technique.

EPA Method 302.0 offers increased bromate specificity without the complexity of post column reactors.

The approved methods for bromate are listed at 40 CFR 141.131(b)(1). The performance characteristics of EPA Method 302.0 were compared to the characteristics of approved EPA Methods 300.1 (USEPA 2000), 317.0, Revision 2.0 (USEPA 2001), and 326.0 (USEPA 2002). EPA has determined that EPA Method 302.0 is equally effective for measuring bromate concentrations as these approved methods. EPA Method 302.0 can also meet the minimum reporting limit (MRL) requirements necessary for methods that are used to support the reduced bromate monitoring specified at 40 CFR 141.132(b)(3)(ii)(B). The basis for these determinations is discussed in Munch 2009a. EPA is therefore approving EPA Method 302.0 for the routine determination of bromate in drinking water and also allowing its use for reduced bromate monitoring. A copy of the method can be accessed and downloaded directly on-line at http://epa.gov/safewater/methods/analyticalmethods_ogwdw.html.

3. EPA Method 557, "Determination of Haloacetic Acids, Bromate, and Dalapon in Drinking Water by Ion Chromatography Electrospray Ionization Tandem Mass Spectrometry (IC-ESI-MS/MS)" (USEPA 2009e) is a direct-injection, ion chromatography, negative-ion electrospray ionization, tandem mass spectrometry (IC-ESI-MS/MS) method for the determination of nine haloacetic acids in finished drinking waters. Each method analyte is qualitatively identified via a unique mass transition, and the concentration is calculated using the integrated peak area and the internal standard technique.

Bromate may be measured concurrently with the haloacetic acids. Real time, chromatographic separation of common anions in drinking water (matrix elimination) is a key feature of this method. Acceptable method performance has been demonstrated for matrix ion concentrations of 320 milligrams/Liter (mg/L) chloride, 250 mg/L sulfate, 150 mg/L bicarbonate and 20 mg/L nitrate.

EPA Method 557 eliminates the labor intensive sample preparation steps (extraction and derivatization) that are required in the current methods that are approved for haloacetic acid determinations. It also reduces the use of solvents and potentially hazardous chemicals. The development work for this method is described in the method

research summary (Zaffiro and Zimmerman 2009).

The sum of five haloacetic acids (monochloroacetic acid, dichloroacetic acid, trichloroacetic acid, monobromoacetic acid, and dibromoacetic acid) is regulated as HAA5. The approved methods for HAA5 are listed at 40 CFR 141.131(b)(1). The performance characteristics of EPA Method 557 for each of the five haloacetic acids were compared to the characteristics of approved EPA Methods 552.2 (USEPA 1995) and 552.3, Revision 1.0 (USEPA 2003) for the same compounds. EPA has determined that EPA Method 557 is equally effective for measuring HAA5 relative to approved EPA Methods 552.2 and 552.3. The basis for this determination is discussed in Munch 2009b. Therefore, EPA is approving EPA Method 557 for determining HAA5 in drinking water.

The performance characteristics of EPA Method 557 were also compared to the bromate-measurement characteristics of approved EPA Methods 300.1 (USEPA 2000), 317.0, Revision 2.0 (USEPA 2001), and 326.0 (USEPA 2002). EPA has determined that EPA Method 557 is equally effective for measuring bromate concentrations as these approved methods. EPA Method 557 can also meet the MRL requirements necessary for methods that are used to support the reduced bromate monitoring specified at 40 CFR 141.132(b)(3)(ii)(B). The basis for these determinations is discussed in Munch 2009b. EPA is therefore approving EPA Method 557 for the routine determination of bromate in drinking water and also allowing its use for reduced bromate monitoring.

A copy of EPA Method 557 can be accessed and downloaded directly on-line at http://epa.gov/safewater/methods/analyticalmethods_ogwdw.html.

4. EPA Method 415.3, Revision 1.2, "Determination of Total Organic Carbon and Specific UV Absorbance at 254 nanometers (nm) in Source Water and Drinking Water" (USEPA 2009f) is a slightly modified version of the currently approved EPA Method 415.3, Revision 1.1 (USEPA 2005). Revision 1.1 is listed as an approved method for determining total organic carbon (TOC), dissolved organic carbon (DOC), ultraviolet absorbance at 254 nm (UV₂₅₄), and specific ultraviolet absorbance (SUVA) concentrations at 40 CFR 141.131(d). Determination of UV₂₅₄ can only be done using a double beam spectrophotometer if the instrument is zeroed according to the directions in the approved method. Since many water

system laboratories use single beam spectrophotometers, the method was revised to allow for their use by modifying the zeroing procedure. This modification did not result in any change in the performance of the method. Therefore, EPA finds that Method 415.3, Revision 1.2 is equally effective as Revision 1.1. Revision 1.2 also corrects some typographical errors that are present in Revision 1.1. The modifications are documented in Wimsatt 2009. EPA is approving EPA Method 415.3, Revision 1.2 for determining TOC, DOC, UV₂₅₄, and SUVA in source water and drinking water.

A copy of EPA Method 415.3, Revision 1.2 can be accessed and downloaded directly on-line at <http://www.epa.gov/nerlcwww/ordmeth.htm>.

B. Methods Developed by Voluntary Consensus Standard Bodies (VCSB)

1. *Standard Methods for the Examination of Water and Wastewater*. Standard Methods 9223 B-97 and 9223 B (20th and 21st Edition) can be used to detect *Escherichia coli* (*E. coli*). Approved methods for *E. coli* are listed at 40 CFR 141.21(f)(6). The Minimal Medium ONPG-MUG (MMO-MUG) Test is listed as an approved method for *E. coli* and the reference cited for the procedure is a journal article (Edberg *et al.* 1989). Standard Methods used the same research documented in the journal article to write Standard Method 9223 B, which is published in the 20th and 21st Edition of *Standard Methods for the Analysis of Water and Wastewater* (APHA 1998, 2005). The same method is also available on-line as Standard Method 9223 B-97 (APHA 1997). Since Standard Methods 9223 B (20th and 21st Edition) and 9223 B-97 are the same procedure as that documented in the Edberg *et al.* article, they are equally effective as the approved Edberg method for determining *E. coli* (Best 2009). Therefore, EPA is approving the use of Standard Methods 9223 B (20th Edition), 9223 B (21st Edition) and 9223 B-97 for determining *E. coli* as specified at 40 CFR 141.21(f)(6). The 20th and 21st editions can be obtained from American Public Health Association (APHA), 800 I Street, NW., Washington, DC 20001-3710. Standard Method 9223 B-97 is available at <http://www.standardmethods.org>.

2. *ASTM International*. EPA compared the most recent versions of 14 ASTM International methods to the versions of those methods cited in 40 CFR 141 and 143. Changes between the approved version and the most recent version of each method are summarized

in Fair 2009. The revisions primarily involve editorial changes (*i.e.*, updated references, reorganization, and corrections of errors). Data generated using the revised methods are comparable to data obtained using the previous versions because the chemistry, sample-handling protocols, and QC are unchanged. The new versions are equally effective relative to the version cited in the regulation (Fair 2009). Therefore, EPA is approving the use of the 14 updated ASTM methods

for the contaminants and regulations listed in the following table.

The revised ASTM method for bromate and chlorite analyses (D 6581–08) is split into two techniques. Method A uses chemically suppressed ion chromatography and is the same as the approved Method D 6581–00, which is listed in the regulation at 40 CFR 141.131(b)(1); ASTM D 6581–08 A is one of the 14 methods previously discussed. Method B uses electrolytically suppressed ion chromatography and represents a new

method. EPA compared the bromate and chlorite performance data for Method B to the data in the approved Method D 6581–00 and determined that Method B is equally effective as the currently approved method (Fair 2009). Therefore, EPA is approving ASTM D 6581–08 B for the determination of bromate and chlorite in routine drinking water compliance samples.

The ASTM methods that are approved in this action are listed in the following table:

| ASTM method | Contaminant | Regulation |
|---------------------------------------|-------------------|-----------------------|
| D511–09 A (ASTM International 2009a) | Calcium | 40 CFR 141.23(k)(1). |
| | Magnesium | 40 CFR 141.23(k)(1). |
| D511–09 B (ASTM International 2009a) | Calcium | 40 CFR 141.23(k)(1). |
| | Magnesium | 40 CFR 141.23(k)(1). |
| D1688–07 A (ASTM International 2009b) | Copper | 40 CFR 141.23(k)(1). |
| D1688–07 C (ASTM International 2009b) | Copper | 40 CFR 141.23(k)(1). |
| D2972–08 B (ASTM International 2009c) | Arsenic | 40 CFR 141.23(k)(1). |
| D2972–08 C (ASTM International 2009c) | Arsenic | 40 CFR 141.23(k)(1). |
| D3559–08 D (ASTM International 2009d) | Lead | 40 CFR 141.23(k)(1). |
| D3645–08 B (ASTM International 2009e) | Beryllium | 40 CFR 141.23(k)(1). |
| D3697–07 (ASTM International 2009f) | Antimony | 40 CFR 141.23(k)(1). |
| D3859–08 A (ASTM International 2009g) | Selenium | 40 CFR 141.23(k)(1). |
| D3859–08 B (ASTM International 2009g) | Selenium | 40 CFR 141.23(k)(1). |
| D1253–08 (ASTM International 2009h) | Free Chlorine | 40 CFR 141.74(a)(2). |
| | Total Chlorine | 40 CFR 141.131(c)(1). |
| | | 40 CFR 141.74(a)(2). |
| | Combined Chlorine | 40 CFR 141.131(c)(1). |
| D516–07 (ASTM International 2009i) | Sulfate | 40 CFR 143.4(b). |
| D6581–08 A (ASTM International 2009j) | Bromate | 40 CFR 141.131(b)(1). |
| | Chlorite | 40 CFR 141.131(b)(1). |
| D6581–08 B (ASTM International 2009j) | Bromate | 40 CFR 141.131(b)(1). |
| | Chlorite | 40 CFR 141.131(b)(1). |

The 15 ASTM methods are available from ASTM International, 100 Barr Harbor Drive, West Conshohocken, PA 19428–2959 or <http://www.astm.org>.

C. Methods Developed by Vendors

1. AMI Turbiwell Method (SWAN Analytische Instrumente AG 2009a) uses light emitting diode (LED) nephelometry to continuously measure turbidity in drinking water. The turbidimeter utilizes a non-contact light source design to avoid fouling of optical surfaces. The LED has an emission range of 415 nm to 780 nm with a peak spectral radiance of 562nm. The light beam from the emission LED impinges the water surface and is refracted. The detector measures the scattered light at an angle of 90°. A light barrier avoids measurement errors due to light reflections. The instrument is equipped with an internal data logger, or the data can be downloaded to a personal computer or central data system with appropriate computer software.

The approved methods for turbidity are listed at 40 CFR 141.74(a)(1). The performance characteristics of the AMI

Turbiwell turbidimeter were compared to the performance characteristics of approved EPA Method 180.1 (USEPA 1993). The validation study report (SWAN Analytische Instrumente AG 2009b) summarizes the results obtained from the turbidimeters placed in series at three different public water systems. One water system used ground water and the other two plants used surface water sources. Measurements included at least one filter backwash at each of the surface water plants.

EPA has determined that the AMI Turbiwell Method is equally effective as approved EPA Method 180.1. The basis for this determination is discussed in the validation study report (SWAN Analytische Instrumente AG 2009b). Therefore, EPA is approving the AMI Turbiwell Method for determining turbidity in drinking water. A copy of the method can be downloaded from the National Environmental Methods Index (NEMI) at <http://www.nemi.gov> or obtained by contacting Markus Bernasconi, SWAN Analytische Instrumente AG, Studbachstrasse 13, CH–8340 Hinwil, Switzerland.

2. ChloroSense (Palintest Ltd 2009a) is an electrochemical sensor method that measures free and total chlorine using disposable sensors. Free and combined available chlorine react with proprietary reagents on the sensor to create intermediate reaction products. These products are then detected electrochemically. The current that flows in each case is proportional to the amount of free available chlorine or total available chlorine in the sample. The sensors are pre-calibrated, and free and total chlorine concentrations are displayed upon completion of the analysis.

Approved methods for determining free and total chlorine residuals in drinking water are listed in the tables at 40 CFR 141.74(a)(2) and 40 CFR 141.131(c)(1). The performance characteristics of ChloroSense were compared to the performance characteristics of approved Standard Methods 4500–Cl D (amperometric titration)(APHA 1998) and 4500–Cl G (DPD colorimetric)(APHA 1998). A variety of samples, including drinking water samples from both surface and

ground water sources, were fortified with known chlorine concentrations and then analyzed by each method. The results are summarized in the validation study report (Palintest Ltd 2009b).

EPA has determined that the ChloroSense Method is equally effective as approved Standard Methods 4500–Cl D and 4500–Cl G. The basis for this determination is discussed in the validation study report (Palintest Ltd 2009b). Therefore, EPA is approving the ChloroSense Method for determining free and total chlorine residuals in drinking water. A copy of the method can be downloaded from NEMI at <http://www.nemi.gov> or obtained by contacting Palintest Ltd, 21 Kenton Lands Road, P.O. Box 18395, Erlanger, KY 41018.

3. Modified Colitag™ (CPI International 2009). Colitag™ (CPI International 2001) is a presence/absence method approved for use under the Total Coliform Rule. It uses enzymatic cleavage of a chromogenic substance to detect total coliforms and enzymatic cleavage of a fluorogenic substance to detect *E. coli* in a 100 mL sample of drinking water. Detection of total coliforms and *E. coli* are performed simultaneously by this method. Colitag™ may also be used in a most-probable-number format provided that the sum of all individual portions of the sample total 100 mL. Modified Colitag™ has a different formulation from the originally approved Colitag™. The purpose of the formula change is to achieve greater selectivity for total coliforms and *E. coli*. Additionally, the Modified Colitag™ provides flexibility in the incubation period (16 to 48 hours), while the approved Colitag™ requires a 24 hour incubation time.

Approved methods for total coliforms are listed at 40 CFR 141.21(f)(3) and approved methods for *E. coli* are listed at 40 CFR 141.21(f)(6). The performance characteristics of Modified Colitag™ were compared to Standard Methods 9221 B (LTB/BGLB) for total coliforms and 9222 G (LTB/EC–MUG) for *E. coli* (APHA 1998). The comparison study involved analyses of twenty replicate drinking water samples that were inoculated with very low densities of chlorine stressed total coliforms or *E. coli* obtained from ten geographically dispersed waste waters. Method specificity was evaluated using 100 positive and 100 negative cultures as determined from analyses by the reference methods.

EPA has determined that the Modified Colitag™ Method is equally effective as approved Standard Methods 9221 B for total coliforms and 9222 G for *E. coli*, which are already promulgated in the

regulations at 40 CFR 141.21(f)(3) and 40 CFR 141.21(f)(6), respectively. The basis for this determination is discussed in the study report (USEPA 2009g). Therefore, EPA is approving the Modified Colitag™ Method for determining total coliforms and *E. coli* in drinking water. A copy of the method can be downloaded from NEMI at <http://www.nemi.gov> or obtained by contacting CPI International, 580 Skylane Boulevard, Santa Rosa, CA 95403.

IV. Statutory and Executive Order Reviews

As noted in Section II, under the terms of SDWA Section 1401(1), this streamlined method approval action is not a rule. Accordingly, the Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, does not apply because this action is not a rule for purposes of 5 U.S.C. 804(3). Similarly, this action is not subject to the Regulatory Flexibility Act because it is not subject to notice and comment requirements under the Administrative Procedure Act or any other statute. In addition, because this approval action is not a rule but simply makes alternative (optional) testing methods available for monitoring under SDWA, EPA has concluded that other statutes and executive orders generally applicable to rulemaking do not apply to this approval action.

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List of Subjects in 40 CFR Part 141

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

Dated: October 29, 2009.

Peter S. Silva,

Assistant Administrator, Office of Water.

■ For the reasons stated in the preamble, 40 CFR part 141 is amended as follows:

PART 141—NATIONAL PRIMARY DRINKING WATER REGULATIONS

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

Authority: 42 U.S.C. 300f, 300g-1, 300j-4, and 300j-9.

■ 2. Appendix A to subpart C of part 141 is amended as follows:

■ a. By revising the entry in the table entitled “Alternative testing methods for contaminants listed at 40 CFR 141.21(f)(3).”

■ b. By adding the table entitled “Alternative testing methods for contaminants listed at 40 CFR 141.21(f)(6)” after the table entitled “Alternative testing methods for contaminants listed at 40 CFR 141.21(f)(3).”

■ c. By revising the entries for “Antimony,” “Arsenic,” “Beryllium,” “Calcium,” “Copper,” “Lead,” “Magnesium,” and “Selenium” in the table entitled “Alternative testing methods for contaminants listed at 40 CFR 141.23(k)(1).”

■ d. By revising the entry for “Turbidity” in the table entitled “Alternative testing methods for contaminants listed at 40 CFR 141.74(a)(1).”

■ e. By revising the entries for “Free Chlorine” and “Total Chlorine” in the

table entitled “Alternative testing methods for disinfectant residuals listed at 40 CFR 141.74(a)(2).”

■ f. By revising the entry for “HAA5” and adding the entries for “Bromate” and “Chlorite” after the entry for “HAA5” in the table entitled “Alternative testing methods for contaminants listed at 40 CFR 141.131(b)(1).”

■ g. By revising the entries for “Free Chlorine,” “Combined Chlorine” and “Total Chlorine” in the table entitled “Alternative testing methods for

disinfectant residuals listed at 40 CFR 141.131(c)(1).”

■ h. By revising all the entries in the table entitled “Alternative testing methods for parameters listed at 40 CFR 141.131(d).”

■ i. By adding the table entitled “Alternative testing methods with MRL ≤ 0.0010 mg/L for monitoring listed at 40 CFR 141.132(b)(3)(ii)(B)” after the table entitled “Alternative testing methods for parameters listed at 40 CFR 141.131(d).”

■ j. By revising the entry for “Sulfate” in the table entitled “Alternative testing methods for contaminants listed at 40 CFR 143.4(b)” and,

■ k. By adding footnotes 13 through 19 to the table.

Appendix A to Subpart C of Part 141— Alternative Testing Methods Approved for Analyses Under the Safe Drinking Water Act

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ALTERNATIVE TESTING METHODS FOR CONTAMINANTS LISTED AT 40 CFR 141.21(f)(3)

| Organism | Methodology | SM 21st edition ¹ | Other |
|-----------------------|--|------------------------------|---------------------------------|
| Total Coliforms | Total Coliform Fermentation Technique | 9221 A, B | Modified Colitag™ ¹³ |
| | Total Coliform Membrane Filter Technique | 9222 A, B, C | |
| | Presence-Absence (P–A) Coliform Test | 9221 D | |
| | ONPG–MUG Test | 9223 | |
| | Colitag™ | | |

ALTERNATIVE TESTING METHODS FOR CONTAMINANTS LISTED AT 40 CFR 141.21(F)(6)

| Organism | Methodology | SM 20th edition ⁶ | SM 21st edition ¹ | SM online ³ | Other |
|----------------------|---------------------|------------------------------|------------------------------|------------------------|---------------------------------|
| <i>E. coli</i> | ONPG–MUG Test | 9223 B | 9223 B | 9223 B–97 | Modified Colitag™ ¹³ |

ALTERNATIVE TESTING METHODS FOR CONTAMINANTS LISTED AT 40 CFR 141.23(k)(1)

| Contaminant | Methodology | EPA method | SM 21st edition ¹ | SM online ³ | ASTM ⁴ | Other |
|----------------------|---|---|------------------------------|------------------------|---------------------------------|--------|
| * Antimony | * Hydride-Atomic Absorption | * 200.5, Revision 4.2. ² | * 3113 B | * * | * D 3697–07 | * * |
| | Atomic Absorption; Furnace | | | | | |
| | Axially viewed inductively coupled plasma-atomic emission spectrometry (AVICP–AES). | | | | | |
| * Arsenic | * Atomic Absorption; Furnace | * 200.5, Revision 4.2. | * 3113 B 3114 B | * * | * D 2972–08 C D 2972–08 B | * * |
| | Hydride Atomic Absorption | | | | | |
| | Axially viewed inductively coupled plasma-atomic emission spectrometry (AVICP–AES). | | | | | |
| * Beryllium | * Inductively Coupled Plasma | * 200.5, Revision 4.2. | * 3120 B 3113 B | * * | * D 3645–08 B | * * |
| | Atomic Absorption; Furnace | | | | | |
| | Axially viewed inductively coupled plasma-atomic emission spectrometry (AVICP–AES). | | | | | |
| * Calcium | * EDTA titrimetric | * 200.5, Revision 4.2. | * 3500–Ca B 3111 B | * * | * D 511–09 A D 511–09 B | * * |
| | Atomic Absorption; Direct Aspiration. | | | | | |
| | Inductively Coupled Plasma | | | | | |
| | Axially viewed inductively coupled plasma-atomic emission spectrometry (AVICP–AES). | | | | | |
| * Copper | * Atomic Absorption; Furnace | * 200.5, Revision 4.2. | * 3113 B 3111 B | * * | * D 1688–07 C D 1688–07 A | * * |
| | Atomic Absorption; Direct Aspiration. | | | | | |
| | Inductively Coupled Plasma | | | | | |

ALTERNATIVE TESTING METHODS FOR CONTAMINANTS LISTED AT 40 CFR 141.23(k)(1)—Continued

| Contaminant | Methodology | EPA method | SM 21st edition ¹ | SM online ³ | ASTM ⁴ | Other |
|-------------|---|----------------------|-------------------------------|------------------------|----------------------------|-------|
| | Axially viewed inductively coupled plasma-atomic emission spectrometry (AVICP–AES). | 200.5, Revision 4.2. | | | | |
| Lead | Atomic Absorption; Furnace Axially viewed inductively coupled plasma-atomic emission spectrometry (AVICP–AES). | 200.5, Revision 4.2. | 3113 B | * | D 3559–08 D | * |
| Magnesium | Atomic Absorption Inductively Coupled Plasma Complexation Titrimetric Methods. Axially viewed inductively coupled plasma-atomic emission spectrometry (AVICP–AES). | 200.5, Revision 4.2. | 3111 B 3120 B 3500–Mg B | | D 511–09 B D 511–09 A | |
| Selenium | Hydride-Atomic Absorption Atomic Absorption; Furnace Axially viewed inductively coupled plasma-atomic emission spectrometry (AVICP–AES). | 200.5, Revision 4.2. | 3114 B 3113 B | * | D 3859–08 A D 3859–08 B | * |

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ALTERNATIVE TESTING METHODS FOR CONTAMINANTS LISTED AT 40 CFR 141.74(a)(1)

| Organism | Methodology | SM 21st edition ¹ | Other |
|-----------|---|------------------------------|---|
| Turbidity | Nephelometric Method Laser Nephelometry (on-line) LED Nephelometry (on-line) LED Nephelometry (on-line) LED Nephelometry (portable) | 2130 B | Mitchell M5271 ¹⁰ Mitchell M5331 ¹¹ AMI Turbiwell ¹⁵ Orion AQ4500 ¹² |

ALTERNATIVE TESTING METHODS FOR DISINFECTANT RESIDUALS LISTED AT 40 CFR 141.74(a)(2)

| Residual | Methodology | SM 21st edition ¹ | ASTM ⁴ | Other |
|----------------|---|---|-------------------|--|
| Free Chlorine | Amperometric Titration DPD Ferrous Titrimetric DPD Colorimetric Syringaldazine (FACTS) On-line Chlorine Analyzer Amperometric Sensor | 4500–Cl D 4500–Cl F 4500–Cl G 4500–Cl H | D 1253–08 | EPA 334.0 ¹⁶ ChloroSense ¹⁷ |
| Total Chlorine | Amperometric Titration Amperometric Titration (Low level measurement) DPD Ferrous Titrimetric DPD Colorimetric Iodometric Electrode On-line Chlorine Analyzer Amperometric Sensor | 4500–Cl D 4500–Cl E 4500–Cl F 4500–Cl G 4500–Cl I | D 1253–08 | EPA 334.0 ¹⁶ ChloroSense ¹⁷ |

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ALTERNATIVE TESTING METHODS FOR CONTAMINANTS LISTED AT 40 CFR 141.131(b)(1)

| Contaminant | Methodology | EPA method | ASTM ⁴ | SM 21st edition ¹ |
|-------------|---|---------------------|-------------------|------------------------------|
| HAA5 | LLE (diazomethane)/GC/ECD | | | 6251 B |
| Bromate | Ion Chromatography Electrospray Ionization Tandem Mass Spectrometry (IC-ESI-MS/MS). | 557 ¹⁴ | | |
| | Two-Dimensional Ion Chromatography (IC) | 302.0 ¹⁸ | | |
| | Ion Chromatography Electrospray Ionization Tandem Mass Spectrometry (IC-ESI-MS/MS). | 557 ¹⁴ | | |
| | Chemically Suppressed Ion Chromatography | | D 6581-08 A | |
| | Electrolytically Suppressed Ion Chromatography | | D 6581-08 B | |
| Chlorite | Chemically Suppressed Ion Chromatography | | D 6581-08 A | |
| | Electrolytically Suppressed Ion Chromatography | | D 6581-08 B | |

ALTERNATIVE TESTING METHODS FOR DISINFECTANT RESIDUALS LISTED AT 40 CFR 141.131(c)(1)

| Residual | Methodology | SM 21st edition ¹ | ASTM ⁴ | Other |
|---------------------------|----------------------------------|------------------------------|-------------------|--|
| Free Chlorine | Amperometric Titration | 4500-CI D | D 1253-08 | ChloroSense ¹⁷ EPA 334.0 ¹⁶ |
| | DPD Ferrous Titrimetric | 4500-CI F | | |
| | DPD Colorimetric | 4500-CI G | | |
| | Syringaldazine (FACTS) | 4500-CI H | | |
| | Amperometric Sensor | | | |
| On-line Chlorine Analyzer | | | | |
| Combined Chlorine | Amperometric Titration | 4500-CI D | D 1253-08 | |
| | DPD Ferrous Titrimetric | 4500-CI F | | |
| | DPD Colorimetric | 4500-CI G | | |
| Total Chlorine | Amperometric Titration | 4500-CI D | D 1253-08 | |
| | Low level Amperometric Titration | 4500-CI E | | |
| | DPD Ferrous Titrimetric | 4500-CI F | | |
| | DPD Colorimetric | 4500-CI G | | |
| | Iodometric Electrode | 4500-CI I | | |
| | Amperometric Sensor | | | |
| | On-line Chlorine Analyzer | | | |
| | | | | ChloroSense ¹⁷ EPA 334.0 ¹⁶ |

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ALTERNATIVE TESTING METHODS FOR PARAMETERS LISTED AT 40 CFR 141.131(d)

| Parameter | Methodology | SM 21st edition ¹ | EPA |
|---|--|------------------------------|------------------------------|
| Total Organic Carbon (TOC) | High Temperature Combustion | 5310 B | 415.3, Rev 1.2 ¹⁹ |
| | Persulfate-Ultraviolet or Heated Persulfate Oxidation. | 5310 C | 415.3, Rev 1.2 |
| Specific Ultraviolet Absorbance (SUVA) | Wet Oxidation | 5310 D | 415.3, Rev 1.2 |
| | Calculation using DOC and UV ₂₅₄ data | | 415.3, Rev 1.2 |
| Dissolved Organic Carbon (DOC) | High Temperature Combustion | 5310 B | 415.3, Rev 1.2 |
| | Persulfate-Ultraviolet or Heated Persulfate Oxidation. | 5310 C | 415.3, Rev 1.2 |
| Ultraviolet absorption at 254 nm (UV ₂₅₄) | Wet Oxidation | 5310 D | 415.3, Rev 1.2 |
| | Spectrophotometry | 5910 B | 415.3, Rev 1.2 |

ALTERNATIVE TESTING METHODS WITH MRL > 0.0010 MG/L FOR MONITORING LISTED AT 40 CFR 141.132(b)(3)(ii)(B)

| Contaminant | Methodology | EPA method |
|-------------|--|---------------------|
| Bromate | Two-Dimensional Ion Chromatography (IC) | 302.0 ¹⁸ |
| | Ion Chromatography Electrospray Ionization Tandem Mass Spectrometry (IC-ESI-MS/MS) | 557 ¹⁴ |

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ALTERNATIVE TESTING METHODS FOR CONTAMINANTS LISTED AT 40 CFR 143.4(b)

| Contaminant | Methodology | EPA Method | ASTM ⁴ | SM 21st edition ¹ | SM Online ³ |
|-------------|--------------------------------------|------------|-------------------|--------------------------------------|---|
| Sulfate | Ion Chromatography | | | 4110 B | |
| | Gravimetric with ignition of residue | | | 4500-SO ₄ ⁻² C | 4500-SO ₄ ⁻² C-97 |
| | Gravimetric with drying of residue | | | 4500-SO ₄ ⁻² D | 4500-SO ₄ ⁻² D-97 |
| | Turbidimetric method | | D 516-07 | 4500-SO ₄ ⁻² E | 4500-SO ₄ ⁻² E-97 |
| | Automated methylthymol blue method | | | 4500-SO ₄ ⁻² F | 4500-SO ₄ ⁻² F-97 |

¹ Standard Methods for the Examination of Water and Wastewater, 21st edition (2005). Available from American Public Health Association, 800 I Street, NW, Washington, DC 20001-3710.

² EPA Method 200.5, Revision 4.2. "Determination of Trace Elements in Drinking Water by Axially Viewed Inductively Coupled Plasma-Atomic Emission Spectrometry." 2003. EPA/600/R-06/115. (Available at <http://www.epa.gov/nerlcwww/ordmeth.htm>.)

³ Standard Methods Online are available at <http://www.standardmethods.org>. The year in which each method was approved by the Standard Methods Committee is designated by the last two digits in the method number. The methods listed are the only online versions that may be used.

⁴ Available from ASTM International, 100 Barr Harbor Drive, West Conshohocken, PA 19428-2959 or <http://astm.org>. The methods listed are the only alternative versions that may be used.

⁶ Standard Methods for the Examination of Water and Wastewater, 20th edition (1998). Available from American Public Health Association, 800 I Street, NW., Washington, DC 20001-3710.

¹⁰ Mitchell Method M5271, Revision 1.1. "Determination of Turbidity by Laser Nephelometry," March 5, 2009. Available at <http://www.nemi.gov> or from Leck Mitchell, Ph.D., PE, 656 Independence Valley Dr., Grand Junction, CO 81507.

¹¹ Mitchell Method M5331, Revision 1.1. "Determination of Turbidity by LED Nephelometry," March 5, 2009. Available at <http://www.nemi.gov> or from Leck Mitchell, Ph.D., PE, 656 Independence Valley Dr., Grand Junction, CO 81507.

¹² Orion Method AQ4500, Revision 1.0. "Determination of Turbidity by LED Nephelometry," May 8, 2009. Available at <http://www.nemi.gov> or from Thermo Scientific, 166 Cummings Center, Beverly, MA 01915, <http://www.thermo.com>.

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¹⁴ EPA Method 557. "Determination of Haloacetic Acids, Bromate, and Dalapon in Drinking Water by Ion Chromatography

Electrospray Ionization Tandem Mass Spectrometry (IC-ESI-MS/MS)," August 2009. EPA 815-B-09-012. Available at http://epa.gov/safewater/methods/analyticalmethods_ogwdw.html.

¹⁵ AMI Turbiwell, "Continuous Measurement of Turbidity Using a SWAN AMI Turbiwell Turbidimeter," August 2009. Available at <http://www.nemi.gov> or from Markus Bernasconi, SWAN Analytische Instrumente AG, Stubbachstrasse 13, CH-8340 Hinwil, Switzerland.

¹⁶ EPA Method 334.0. "Determination of Residual Chlorine in Drinking Water Using an On-line Chlorine Analyzer," August 2009. EPA 815-B-09-013. Available at http://epa.gov/safewater/methods/analyticalmethods_ogwdw.html.

¹⁷ ChloroSense. "Measurement of Free and Total Chlorine in Drinking Water by Palintest ChloroSense," September 2009. Available at <http://www.nemi.gov> or from Palintest Ltd, 21 Kenton Lands Road, PO Box 18395, Erlanger, KY 41018.

¹⁸ EPA Method 302.0. "Determination of Bromate in Drinking Waters using Two-Dimensional Ion Chromatography with Suppressed Conductivity Detection," September 2009. EPA 815-B-09-014. Available at http://epa.gov/safewater/methods/analyticalmethods_ogwdw.html.

¹⁹ EPA 415.3, Revision 1.2. "Determination of Total Organic Carbon and Specific UV Absorbance at 254 nm in Source Water and Drinking Water," August 2009. EPA/600/R-09/122. Available at <http://www.epa.gov/nerlcwww/ordmeth.htm>.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

42 CFR Part 52

[Docket No. NIH-2007-0929]

RIN 0925-AA42

Grants for Research Projects

AGENCY: National Institutes of Health, Department of Health and Human Services.

ACTION: Final rule.

SUMMARY: The National Institutes of Health is amending the current regulations governing grants for research projects by revising the definition of Principal Investigator to mean one or more individuals designated by the grantee in the grant application and approved by the Secretary, who is or are responsible for the scientific and technical direction of the project, rather than limiting the role of Principal Investigator to one single individual; and the conditions for multiple or concurrent awards pursuant to one or more applications.

DATES: This final rule is effective December 10, 2009.

FOR FURTHER INFORMATION CONTACT: Jerry Moore, NIH Regulations Officer, Office of Management Assessment, National Institutes of Health, 6011 Executive Boulevard, Room 601, MSC 7669, Rockville, MD 20852-7669, or telephone 301-496-4607.

SUPPLEMENTARY INFORMATION: On September 30, 2003, the NIH Director announced a series of far reaching strategic initiatives known collectively as the NIH Roadmap for Medical Research (NIH Roadmap). The NIH Roadmap is an innovative approach designed to transform the Nation's medical research capabilities and accelerate fundamental research discovery and translation of that knowledge into effective prevention strategies and new treatments. One of the NIH Roadmap initiatives encourages interdisciplinary research and team science and includes a recommendation to modify grant and research contract applications to allow for the proposing of more than one Principal Investigator when appropriate. This is congruent with the January 4, 2005, directive issued by the Office of Science and Technology Policy (OSTP) to all Federal research agency heads instructing the heads to accommodate the recognition of two or more Principal Investigators on research projects (grants and contracts). This OSTP policy does not prohibit the use of a single Principal