

TABLE 1.—PM POST-REBUILD LEVELS (G/BHP-HR) FOR CALCULATING TLFs FOR CALENDAR YEAR 2000 AND THEREAFTER¹—Continued

Engine model	Model year	Pre-rebuild level	Post-Rebuild level ²	Engine code	Engine family
DDC 6V71N	1973–87	0.50	0.38	All	All.
DDC 6V71N	1988–89	0.50	0.38	All	All.
DDC 6V71T	1985–86	0.50	0.38	All	All.
DDC 8V71N	1973–84	0.50	0.38	All	All.
DDC 6L71TA	1990	0.59	0.59	All	All.
DDC 6L71TA	1988–89	0.31	0.23	All	All.
DDC 6V71TA DDEC ..	1990–91	0.30	0.23	All	All.
DDC 8V92TA	1979–87	0.50	0.38	All	8V92TA.
	1988	0.39	0.29	All	8V92TA.
DDC 8V92TA DDEC ..	1988	0.41	0.31	All	8V92TA–DDEC II.
DDC 8V92TA	1989	0.47	0.35	9E70	KDD0736FW89.
DDC 8V92TA	1989	0.39	0.29	9A90	KDD0736FW89.
DDC 8V92TA	1989	0.34	0.26	9G85	KDD0736FW89.
DDC 8V92TA DDEC ..	1989	0.41	0.31	1A	KDD0736FZH4.
DDC 8V92TA	1990	0.47	0.35	9E70	LDD0736FAH9.
DDC 8V92TA DDEC ..	1990	0.49	0.37	1A	LDD0736FZH3.
DDC 8V92TA DDEC ..	1991	0.25	0.19	1A or 5A	MDD0736FZH2.
DDC 8V92TA DDEC ..	1992–93	0.21	0.16	1D	NDD0736FZH1 & PDD0736FZH X.
DDC 8V92TA DDEC ..	1992–93	0.29	0.22	6A	NDD0736FZH 1 & PDD0736FZH X.
DDC 8V92TA DDEC ..	1992–93	0.20	0.15	5A	NDD0736FZH 1 & PDD0736FZH X.
DDC 8V92TA DDEC ..	1992–93	0.25	0.19	1A	NDD0736FZH 1 & PDD0736FZH X.
CUMMINS L–10	1985–1987	0.65	0.34	All	All.
	1988–1989	0.55	0.34	All	All.
	1990–1992	0.46	0.34	All	All.
L–10EC	1992	0.25	0.19	All	All.
Cummins L–10 EC w/trap.	1993	0.05	0.05	All	All.
Alternatively-Fueled Engines.	pre–1994	0.10	0.10	All	All.
Other Engines	pre–1988	0.50	0.50	All	All.
	1988–1993	Cert'n Level ³	Cert'n Level ³	All	All.

¹ In accordance with 40 CFR 85.1403(c)(1)(iv).

² The instructions for the spreadsheet list these levels as post-rebuild-3 levels. The instructions are available upon request from the contact listed above.

³ Use the certification level determined under EPA's new engine certification program.

An urban bus operator choosing to comply with Option 2 must be able to demonstrate at all times in a specified year that its fleet level attained (FLA) is equal to or less than its TLF for that year. Using the formulas in 40 CFR 85.1403(c)(1) and the PM emissions levels (including the above post-rebuild levels) in accordance with section 85.1403(a)(1)(iv), operators choosing Option 2 must calculate their TLF for calendar year 2000 and thereafter. The FLA is calculated using the formula of 40 CFR 85.1403(c)(2) and the certification level of the specific equipment installed on each bus. In order to ensure it is in compliance with its TLF at the start of calendar year 2000 and thereafter, transit operators choosing to comply with Option 2 are expected to begin taking appropriate actions (such as installing certified equipment and/or retiring buses) no later than calendar year 1999.

Dated: May 21, 1999.
Robert Perciasepe,
Assistant Administrator for Air and Radiation.
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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 136

[FRL–6354–3]

RIN 2040–AD07

Guidelines Establishing Test Procedures for the Analysis of Pollutants; Measurement of Mercury in Water (EPA Method 1631, Revision B); Final Rule

AGENCY: Environmental Protection Agency (EPA).
ACTION: Final rule.

SUMMARY: This final regulation amends the “Guidelines Establishing Test Procedures for the Analysis of Pollutants” under section 304(h) of the Clean Water Act by adding EPA *Method 1631, Revision B: Mercury in Water by Oxidation, Purge and Trap, and Cold Vapor Atomic Fluorescence Spectrometry*. EPA Method 1631 measures mercury at the low levels associated with ambient water quality criteria (WQC). EPA has promulgated WQC for mercury at 12 parts-per-trillion (ppt) in the National Toxics Rule, and published a criterion for mercury at 1.3 ppt in the Water Quality Guidance for the Great Lakes System. The version of Method 1631 promulgated today includes changes to the method based on public comments at proposal (63 FR 28867, May 26, 1998). These changes increase measurement reliability at WQC levels. EPA recommends the use of clean sampling and laboratory techniques in conjunction with EPA Method 1631 to preclude contamination

at the low ppt levels necessary for mercury determinations. EPA has published guidance documents on sampling and clean rooms for trace metals, including mercury.

EFFECTIVE DATE: This regulation is effective July 8, 1999. For judicial review purposes, this final rule is promulgated as of 1:00 p.m. Eastern Standard Time on June 22, 1999 in accordance with 40 CFR 23.7.

The incorporation by reference of EPA Method 1631 is approved by the Director of the Federal Register July 8, 1999.

ADDRESSES: Copies of the public comments received, EPA responses, and all other supporting documents (including references included in this notice) are available for review at the U.S. Environmental Protection Agency, Water Docket, 401 M Street SW, Washington, DC 20460. For access to docket materials, call 202/260-3027 on Monday through Friday, excluding Federal holidays, between 9 a.m. and 3:30 p.m. Eastern Standard Time for an appointment.

Copies of EPA Method 1631 are available from the National Technical Information Service (NTIS), 5285 Port Royal Road, Springfield, VA 22161, (703) 605-6000 or (800) 553-6847. The NTIS publication number is PB99-131989.

An electronic version of EPA Method 1631 also is available via the Internet at <http://www.epa.gov/OST/Methods>.

FOR FURTHER INFORMATION CONTACT: For information regarding EPA Method 1631 contact Maria Gomez-Taylor, Ph.D., Engineering and Analysis Division (4303), USEPA Office of Science and Technology, 401 M Street, SW, Washington, DC 20460; or call 202/260-1639.

SUPPLEMENTARY INFORMATION:

Potentially Regulated Entities

EPA Regions, as well as States, Territories and Tribes authorized to implement the National Pollutant Discharge Elimination System (NPDES) program, issue permits that comply with the technology-based and water quality-based requirements of the Clean Water Act. In doing so, the NPDES permitting

authority, including authorized States, Territories, and Tribes, make a number of discretionary choices associated with permit writing, including the selection of pollutants to be measured and, in many cases, limited in permits. If EPA has "approved" standardized testing procedures (i.e., promulgated through rulemaking) for a given pollutant, the NPDES permit must include one of the approved testing procedures or an approved alternate test procedure. Regulatory entities may, at their discretion, require use of this method in their permits. Therefore, entities with NPDES permits could be affected by the standardization of testing procedures in this rulemaking, because NPDES permits may incorporate the testing procedures in today's rulemaking. In addition, when a State, Territory, or authorized Tribe provides certification of federal licenses under Clean Water Act section 401, States, Territories and Tribes are directed to use the standardized testing procedures. Categories and entities that may ultimately be affected include:

Category	Examples of potentially regulated entities
Regional, State and Territorial Governments and Indian Tribes	States, Territories, and Tribes authorized to administer the NPDES permitting program; States, Territories, and Tribes providing certification under Clean Water Act section 401; Governmental NPDES permittees.
Industry	Industrial NPDES permittees.
Municipalities	Publicly-owned treatment works with NPDES permits.

This table is not intended to be 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 affected. 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.

Outline of Preamble

- I. Authority
- II. Background
- III. Summary of Final Rule
 - A. Introduction
 - B. Summary of EPA Method 1631
 - C. Sample Contamination
 - D. Quality Control
 - E. Performance-Based Measurement System
- IV. Changes to EPA Method 1631 Since Proposal
 - A. Holding Time Change
 - B. Performance Criteria Change
 - C. Reporting Requirements Changes
 - 1. Reporting of data that failed to meet QC acceptance criteria

- 2. Reporting of blank results
- 3. Reporting laboratory-specific MDLs and MLs
- D. Other Changes and Improvements
 - 1. Changes to method implementation
 - 2. Corrections to method
 - 3. Clarifying statements
 - 4. Additions to health and safety monitoring and waste management
- V. Public Participation and Response to Comments
 - 1. Support for EPA Method 1631
 - 2. Practicality and cost
 - 3. EPA Method 1631 represents a significant regulatory action
 - 4. Regulatory implications
 - 5. Retention of approved methods and approval of additional methods
 - 6. Application to wastewater matrices
 - 7. Detection and quantitation
 - 8. Clean techniques
 - 9. Corrections to statements in proposal
 - 10. Quality control
 - 11. Blanks and contamination
 - 12. Validation study
 - 13. Technical details of EPA Method 1631
 - 14. Miscellaneous
- VI. Regulatory Requirements
 - A. Executive Order 12866
 - B. Unfunded Mandates Reform Act
 - C. Regulatory Flexibility Act
 - D. Paperwork Reduction Act

- E. Submission to Congress and the General Accounting Office
- F. National Technology Transfer and Advancement Act
- G. Executive Order 13045
- H. Executive Order 12875
- I. Executive Order 13084

I. Authority

Today's regulation is being promulgated pursuant to the authority of sections 301, 304(h), and 501(a) of the Clean Water Act (CWA), 33 U.S.C. 1314(h), 1361(a) (the "Act"). Section 301 of the Act prohibits the discharge of any pollutant into navigable waters unless the discharge complies with a National Pollutant Discharge Elimination System (NPDES) permit issued under section 402 of the Act. Section 304(h) of the Act requires the Administrator of the EPA to "promulgate guidelines establishing test procedures for the analysis of pollutants that shall include the factors which must be provided in any certification pursuant to section 401 of this Act or permit applications pursuant to section 402 of this Act." Section 501(a) of the Act authorizes the Administrator to

"prescribe such regulations as are necessary to carry out his function under this Act." EPA publishes CWA analytical method regulations at 40 CFR part 136. The Administrator also has made these test procedures applicable to monitoring and reporting of NPDES permits (40 CFR part 122, §§ 122.21, 122.41, 122.44, and 123.25), and implementation of the pretreatment standards issued under section 307 of the Act (40 CFR part 403, §§ 403.10 and 402.12).

II. Background

The details of EPA Method 1631 and its use in mercury determinations were given at proposal on May 26, 1998 (63 FR 28867). On March 5, 1999, EPA published a notice of data availability (NODA) with results from additional studies of municipal and industrial effluents using EPA Method 1631 (64 FR 10596). EPA conducted the additional studies in order to better respond to comments received on the May 26, 1998 proposal.

III. Summary of Final Rule

A. Introduction

Today's action makes available at 40 CFR part 136 an additional test procedure for measurement of mercury in aqueous samples. This rulemaking does not repeal any of the currently approved methods that measure mercury. For an NPDES permit, the permitting authority should decide the appropriate method based on the circumstances of the particular water sample measured. Use of EPA Method 1631 may be specified by the permitting authority when a permit is modified or reissued.

EPA does not intend for Method 1631 to be a *de facto* replacement for Method 245.1 or any of the other existing EPA-approved methods for measurement of mercury. EPA intends that permit writers specify the use of Method 1631 when measurement at very low levels is required, for example, to determine compliance with water quality-based effluent limitations duly established at very low levels.

B. Summary of EPA Method 1631

EPA Method 1631 has four procedural components: sample pretreatment; purge and trap; desorption; and detection by atomic fluorescence. In the sample pretreatment step, bromine monochloride (BrCl) is added to the sample to oxidize all forms of mercury to Hg(II). After oxidation, the sample is sequentially pre-reduced with $\text{NH}_2\text{OH}\cdot\text{HCl}$ to destroy free halogens, then reduced with SnCl_2 to convert Hg(II) to volatile

Hg(0). The Hg(0) is purged from the aqueous solution with nitrogen onto a gold-coated sand trap. The trapped mercury is thermally desorbed from the gold trap into a flowing gas stream into the cell of a cold-vapor atomic fluorescence spectrometer. Quality is assured through calibration and testing of the oxidation, purging, and detection systems.

C. Sample Contamination

Trace levels of metals are ubiquitous in the environment. Therefore, the determination of trace metals at the levels of interest for water quality criteria necessitates the use of clean sample handling techniques to avoid "false positive" test results due to contamination in the course of sample collection, handling, or analysis. EPA has distributed several guidance documents that are designed to ensure that data results from the measurement of metals in aqueous test samples accurately reflect actual environmental levels. The guidance documents include: *Method 1669: Sampling Ambient Water for Trace Metals at EPA Water Quality Criteria Levels* (Sampling Guidance), EPA-821-R-96-001, July 1996; *Guidance on Establishing Trace Metals Clean Rooms in Existing Facilities*, EPA-821-B-96-001, January 1996; and *Guidance on Documentation and Evaluation of Trace Metals Data Collected for Clean Water Act Compliance Monitoring*, EPA-821-B-96-004, July 1996. The most serious problem faced by laboratories conducting metals analyses at these very low levels is the potential for sample contamination during sample collection and handling. Sample contamination with mercury is particularly difficult to control because of its ubiquity in the environment. For example, commonly used polyethylene sample containers are unacceptable for sample storage because atmospheric mercury may diffuse through the walls of the container causing sample contamination. The Sampling Guidance details rigorous sample handling and quality control (QC) procedures to assure that reliable data are obtained for mercury at the levels of interest for water quality criteria. EPA recommends that the procedures described in the Sampling Guidance be followed when performing low level, trace metals analyses and has incorporated certain essential elements of the Guidance in the method.

D. Quality Control

EPA Method 1631 contains all of the standardized QC tests proposed in EPA's streamlining initiative (62 FR

14976, March 28, 1997) and used in test procedures in 40 CFR part 136, appendix A. Today's rule requires an initial demonstration of laboratory capability which consists of: (1) A method detection limit (MDL) study to demonstrate that the laboratory is able to achieve the MDL and minimum level of quantification (ML) specified in EPA Method 1631; and (2) an initial precision and recovery (IPR) test, consisting of analyses of four reagent water samples spiked with mercury, to demonstrate the laboratory's ability to generate acceptable precision and recovery.

Today's rule also requires ongoing QC tests for each analytical batch, (i.e., a set of 20 samples or less pretreated at the same time):

- Verification of calibration of the purge and trap and atomic fluorescence systems to assure that instrument response has not deviated significantly from the instrument response obtained during calibration.
- Analysis of a matrix spike (MS) and matrix spike duplicate (MSD) to demonstrate method accuracy and precision and to monitor matrix interferences.
- Analysis of reagent and bubbler blanks to demonstrate freedom from contamination.
- Analysis of a quality control sample (QCS) and ongoing precision and recovery (OPR) samples to demonstrate that the method remains under control.

EPA Method 1631 contains QC acceptance criteria for all QC tests. Compliance with these criteria will allow a data user to evaluate the quality of the results. These QC acceptance criteria will increase the reliability of results and provide a means for laboratories and data users to monitor analytical performance, thereby providing a basis for sound, defensible data.

E. Performance Based Measurement System

On March 28, 1997, EPA proposed a rule (62 FR 14976) to streamline approval procedures and use of analytic methods in water programs through implementation of a performance-based approach to environmental measurements. On October 7, 1997, EPA published a document of the Agency's intent to implement a Performance Based Measurement System (PBMS) in all media programs to the extent feasible (62 FR 52098). EPA's water program offices are developing plans to implement PBMS. EPA anticipates that the final rule to implement PBMS in water programs will be published in 1999 based on the March 28, 1997

proposed rule. Consistent with Agency PBMS implementation plans, EPA Method 1631 incorporates QA and QC acceptance criteria to serve as a basis for assessment of method performance. When PBMS is in place, EPA Method 1631 would serve as a reference method for demonstrating equivalency when modifications are made.

EPA Method 1631 also employs a performance-based approach to the sample preparation and trapping systems. Analysts are allowed to modify the sample preparation and trapping aspects of the method provided all the specified performance criteria are demonstrated and documented. The method also allows the use of alternate reagents and hardware provided that the analyst demonstrates equivalent or superior performance and meets all QC acceptance criteria.

Demonstrating equivalency involves two sets of tests, one set with reference standards and the other with the sample matrix. The equivalency procedures include performance of the IPR test using reference standards to demonstrate that the results produced with the modified procedure would meet or exceed the QC acceptance criteria in EPA Method 1631. In addition, if the detection limit would be affected by a modification, performance of an MDL study is required to demonstrate that the modified procedure could achieve an MDL less than or equal to the MDL in EPA Method 1631 or, for those instances in which the regulatory compliance limit is greater than the ML in the method, one-third the regulatory compliance limit. For a discussion of these levels, see EPA Method 1631 or the March 28, 1997 proposed rule at 62 FR 14976.

IV. Changes to EPA Method 1631 Since Proposal

The Agency has revised EPA Method 1631, Revision A based on comments received on the proposal (63 FR 28868, May 26, 1998) and the NODA (64 FR 10596; March 5, 1999). The significant modifications in EPA Method 1631, Revision B are the change of the sample holding time (from 6 months to 28 days), the change of the MS/MSD performance criteria (for recovery from 75–125 percent to 71–125 percent recovery), and a change in reporting requirements.

A. Holding Time Change

EPA proposed the 6 month holding time for preserved aqueous samples to be analyzed by EPA Method 1631. Because the 6 month holding time was not evaluated in the method validation study supporting the proposal, EPA

requested data that would support the 6 month holding time. Data were not available. Therefore, in the version of EPA Method 1631 being approved for use today, EPA has set the holding time to 28 days, the prescribed holding time listed in Table II at 40 CFR part 136.

B. Performance Criteria Change

The MS/MSD recovery limits in the proposed version of EPA Method 1631 were 75–125 percent. The interlaboratory method validation study produced MS/MSD limits of 71–119 percent. In response to comments on the proposal, EPA acknowledges that the lower limit produced in the interlaboratory study is more appropriate and has changed this limit to 71 percent in the version of EPA Method 1631 approved for use today.

C. Reporting Requirements Change

1. Reporting of Data That Failed To Meet QC Acceptance Criteria

In order to clarify the Agency's intent regarding data that do not meet the method QC acceptance criteria or that indicate the analytical system is not in control, EPA has adopted suggestions from commenters that these data should not be reported or otherwise used for permitting or regulatory compliance purposes. This modification addresses concerns that regulated entities could be adversely affected by data not meeting performance criteria, for example, via compliance monitoring. EPA also has added a statement to section 13.2 of the method that any decision not to report data from an analytical system that is out of control does not provide relief from a permit's underlying requirement to submit timely reports.

2. Reporting of Blank Results

In today's rule, EPA has expanded reporting of blank results to include reagent blanks and field blanks so that a regulatory authority may consider field blank contamination in any compliance determination. To facilitate assessment of the presence and extent of contamination, the Agency has revised EPA Method 1631 to require reporting of the mercury concentration in field blanks as well as in reagent blanks. Today's rule, however, does not require blank subtraction. Regulatory authorities or other data users may subtract the concentration of mercury in field blanks or reagent blanks if subtraction is warranted on a case-by-case basis. Today's rule does nothing, however, to preclude the reporting of blank-subtracted results in addition to the separate reporting of results from samples and from blanks.

3. Reporting Laboratory-Specific MDLs and MLS

EPA has removed the option for laboratories to calculate their own lower MDLs and MLs in the version of EPA Method 1631 being approved for use today. EPA believes this will avoid confusion and preclude lower MDLs and MLs from being used for NPDES permitting or regulatory compliance determinations.

D. Other Changes and Improvements

1. Changes To Method Implementation

Minor technical improvements were made to EPA Method 1631 to clarify method implementation. Changes and improvements include:

- Revision to sections 7.9, 7.10 and 10.1.1.2 to include two working standards (0.10 ng/mL and 10.0 ng/mL) in order to correct inaccurate standard concentration levels.
- Language changes in sections 4.4.1 and 9.3.4.1 to address iodide interferences that have been identified and assessed since proposal. This modification required the addition of a reference supporting the handling of iodide interferences. The additional reference has been added to EPA Method 1631 as Reference 10.
- Revisions to sections 9.4.2.2 and 11.1.1.2 to include a requirement that a reagent blank include the same amount of reagent as the sample being analyzed.
- Revisions to section 11.1.1.2 to include recommendations to assure that complete oxidation has occurred.
- Where appropriate, the word "analyst" was changed to "laboratory" to acknowledge that various sections of EPA Method 1631 may be performed by different analysts in the same laboratory.

2. Corrections To Method

Minor changes were made to correct typographical and information errors. Nearly all of the corrections are the result of comments and include:

- In section 9.1.2.1, "less than" was changed to "less than or equal to." A method modification must achieve an MDL "less than or equal to" one-third the compliance limit or the MDL.
- In section 12.4.1, > 0.2 ng/L has been corrected to < 0.2 ng/L.
- In Table 2, (s) has been corrected to RSD for precision.
- In Table 1, the lowest ambient water quality criterion has been corrected from 1.8 ng/L (human health criterion) to 1.3 ng/L (wildlife criterion).

The lowest WQC for the Great Lakes is 1.3 ng/L, the criterion for wildlife protection (see Table 4 to 40 CFR part 132).

- In section 4.2, Reference 5 has been changed to Reference 9, which is a paper discussing contamination of samples by dental work containing mercury amalgam fittings.

- References 10 through 20 in the proposed version of EPA Method 1631 have been changed to References 11 through 21 in the final version to include the addition of a new Reference 10 addressing handling of samples containing iodide interferences.

3. Clarifying Statements

As a result of comments:

- In section 4.3.8.5, a statement was added to clarify that reagents can be a source of contamination.

- Sections 4.3.8.2 and 5.3 were modified to clarify the meaning of "high" concentration of mercury and to caution that samples containing mercury concentrations greater than 100 ng/L should be diluted prior to bringing them into the clean room or laboratory dedicated to processing trace metals samples and that samples containing μ g/L concentrations of mercury should be treated as hazardous.

4. Additions To Health and Safety Monitoring and Waste Management

Today's version of EPA Method 1631 includes two additions made to address and clarify health and safety monitoring and waste management.

- In section 5.2, EPA added a recommendation that personal hygiene monitoring should be performed using Occupational Safety and Health Administration (OSHA) or National Institute of Occupational Safety and Health (NIOSH) approved personal hygiene monitoring methods.

- In section 15.1, a reference was added to address waste management techniques: *Environmental Management Guide for Small Laboratories* (EPA 233-B-98-001). None of the changes or improvements to the Method discussed above warrant re-proposal because these changes merely respond to public comment to clarify, correct minor errors, or otherwise improve the Method. None of these changes impair method performance or reliability.

V. Public Participation and Response to Comments

The Agency proposed EPA Method 1631 ("Method 1631"; or "the Method") on May 26, 1998 (63 FR 28867). The comment period closed on July 27, 1998. In addition to providing notice of the Method, the proposal also solicited

information and data that might be relevant to the Agency's decisionmaking. EPA both received information and data and developed additional data confirming the proposal. EPA issued a notice of data availability (NODA) and request for comment on these data (64 FR 10596; March 5, 1999). The NODA comment period closed on April 5, 1999. During the NODA comment period, EPA again solicited additional data and information on EPA Method 1631.

EPA received more than 500 detailed comments from approximately 30 commenters. Comments ranged from praise and support for EPA Method 1631 to concern about the possible setting of compliance limits at the MDL or ML and suggestions for improving the technical details of the method. EPA appreciates the constructive comments and suggestions and believes that today's version of EPA Method 1631 will provide reliable data for compliance monitoring. A summary of the significant comments is presented below, followed by EPA's response. See the Docket for a complete summary of the detailed comments and more extensive responses.

A significant report received during the comment period was provided by the Department of Environmental Protection (DEP) in the State of Maine titled: "Mercury in Wastewater: Discharges to the Waters of the State" (the "Maine Report"). The Maine Report gives details and results of analysis of 104 ambient water samples and more than 150 wastewater samples (primarily effluents) using the proposed version of EPA Method 1631. The Maine Report is exemplary in that it allowed Maine's DEP to assess the presence and concentration of mercury Statewide, and will allow the State of Maine to focus its resources on problem areas within the State. The Maine Report is also significant because it provided a comprehensive "real world" assessment of the measurement capability of EPA Method 1631. The Maine Report demonstrates that EPA Method 1631 can be applied successfully to determination of mercury in a wide variety of effluents and ambient waters. Of particular interest is that, of 104 ambient water samples tested, no sample contained mercury at a concentration greater than 7 ng/L. Of the more than 100 effluent samples tested, only one contained mercury above the 200 ng/L level that previously approved methods for mercury could have measured. EPA has placed a copy of the Maine Report in the Docket for today's final rule. EPA recommends that all persons interested in making reliable mercury

measurements in ambient water and discharges read the Maine Report. EPA publicly thanks the State of Maine and particularly the Department of Environmental Protection for its contribution. Comments and responses are organized and presented by subject area.

1. Support for EPA Method 1631

Comment: Commenters strongly support the need to reliably measure mercury levels in ambient waters. The method is technically sound and the chemistry behind the method is superb. The Agency should move aggressively to implement this method. Permitting authorities and others should take the necessary steps to see its adoption and use. EPA Method 1631 will: (1) Allow gathering of the type of information crucial to understanding mercury in the environment; (2) allow better analytical information on the levels of mercury in various waters to help decide if and where source reduction efforts would be most effective; (3) allow facilities to better assess actual discharges and progress in reducing mercury in effluents; (4) allow permitting authorities to establish appropriate limits based on ecological or human health endpoints, rather than being limited by the less-sensitive analytical techniques routinely utilized; (5) allow agencies to better monitor reduction of ambient waters to mercury reduction initiatives; (6) be useful for situations in which an authority or facility believes that results obtained with currently approved methods do not reflect actual levels because of contamination during sample collection, handling, and analysis; and (7) allow the State of Wisconsin to meet the recommendations of the "Wisconsin Strategy for Regulating Mercury in Wastewater." The Wisconsin strategy recommends development of better analytical capability to adequately quantify the level of mercury at effluent levels that have the potential to cause environmental degradation.

Response: EPA appreciates the support and, in particular, the recognition that a method for measuring mercury at ambient water quality criteria levels is overdue, that the method is based on sound science, and that EPA Method 1631 will protect dischargers from false reports that mercury is present in an effluent when, in fact, inadequate sampling and laboratory procedures accounted for the mercury measured in the sample.

2. Practicality and Cost

Impractical and Costly

Comment: The required use of EPA Method 1631 would impose an economic burden on industry, would force purchase of expensive new equipment, and would require a significant increase in operating expenses. The cost of a Class 100 clean room is \$50,000–\$200,000. The analytical equipment will cost \$10,000–\$45,000. Fluoropolymer bottles will cost an estimated \$7,200. The bottle cleaning protocol would require dedicated laboratory space and staff. Additional cost will be incurred for training.

Response: Not every facility will need to create a clean room and bottle cleaning capacity, because commercial laboratories are available and can supply clean bottles. In a study conducted by Ford Motor Company, the cost per sample analysis was in the range of \$50–\$80. EPA's experience is that costs per sample typically range between \$50 to \$110. EPA does not believe that this cost is unreasonable. If a facility desires to establish a laboratory for analysis using EPA Method 1631, however, EPA has provided guidance for establishment of "clean spaces" that will minimize costs in establishing a "clean" facility (see References 6 and 7 in Method 1631).

Lack of Laboratory Capability

Comment: Relatively few laboratories nationwide currently have the expertise and infrastructure to conduct analysis using this Method.

Response: Not every laboratory will need to establish the capability to conduct EPA Method 1631. Analytical costs are likely to decrease as demand for and use of the Method increases. Today more than ever, laboratories and other businesses respond rapidly to new business opportunities. Therefore, the Agency anticipates that capacity will develop rapidly as the demand increases for analyses by EPA Method 1631.

Sampling With EPA Method 1669

Comment: Required use of the radical field sampling procedures in EPA Sampling Method 1669 to support EPA Method 1631 would significantly increase cost and staff necessary to sample for mercury analysis alone. One additional sampling person (for clean hands/dirty hands) and ultraclean sampling protocols will cost approximately \$34,000.

Response: Once sampling personnel become familiar with the "clean hands/dirty hands" technique and procedures recommended in EPA Methods 1631

and 1669, sampling for mercury can proceed quickly and efficiently. EPA does not believe that full-time sampling personnel will be needed. EPA anticipates that samples may need to be collected monthly, quarterly, or yearly, depending on the facility and whether mercury is measured at levels of concern. Therefore, the actual incremental cost for collection of samples using the techniques suggested in EPA Method 1669 will be small.

3. EPA Method 1631 Represents a Significant Regulatory Action

Significant Regulatory Action Under Executive Order 12866

Comment: The proposed rule is a "Significant Regulatory Action" under Executive Order 12866 (58 FR 51735, Oct. 4, 1993).

Response: It has been determined that this rule is a significant regulatory action and was, therefore, reviewed by the Office of Management and Budget (OMB).

Cost Increase Stated in Great Lakes Guidance

Comment: EPA acknowledged in Table 5–13 of *Assessment of Compliance Costs Resulting from Implementation of the Final Great Lakes Water Quality Guidance* (the "Assessment Document") that the annual cost could increase by \$569.8 million if future MDLs became 10 times lower and could increase by \$882.5 million if future MDLs became 100 times lower. EPA Method 1631 lists an MDL 1000 times lower. This rule should be subject to OMB review.

Response: The estimated compliance cost increases in the Assessment Document referred to future MDLs for all toxic pollutants (not just mercury) assuming MDLs might be used as compliance limits (and the MDL used for compliance evaluation). The Assessment Document states that the minimum level (ML), not the MDL, should be used for compliance evaluation when the WQBEL is below the detection or quantitation limit of the most sensitive analytical method. Today's rule implicates neither of these limits (MDL nor ML) because EPA Method 1631 allows reliable measurements below the lowest ambient water quality criterion (1.3 ng/L) in the final Great Lakes Water Quality Guidance. The Assessment Document presumed that costs would increase if dischargers were required to meet discharge requirements at the lower MDLs, not that it would cost these amounts if EPA allowed use of another method for the measurement of

mercury. In any event, EPA evaluated compliance costs in the Great Lakes rulemaking because it would result in establishment of standards of compliance. Today's rule does not set standards of compliance, only standards of measurement and analysis. This rule is considered a significant regulatory action and was, therefore, reviewed by OMB.

Unfunded Mandates Reform Act

Comment: The Unfunded Mandates Reform Act (UMRA; 25 U.S.C. 1531, Subchapter II), requires assessment of the effects of regulatory actions on the private sector and preparation of a statement containing qualitative/quantitative cost-benefit analysis if costs are expected to exceed \$100 million. EPA should perform the cost and benefit assessments because existing permits require the use of the most sensitive test procedure.

Response: EPA acknowledges that some permits may require the permittee to use the most sensitive test procedure available at the time of permit issuance, for example, when the limit is below detection of approved methods. Today's rulemaking does not automatically change permits issued prior to today. The only costs associated with today's rule are analytical costs, not compliance costs. Today's rule is not subject to the requirements of sections 202 and 205 of UMRA because it does not contain a Federal mandate that could result in expenditures of \$100 million or more for State, local, and tribal governments, in the aggregate, or the private sector in any one year. EPA estimates the incremental analytical costs associated with the use of EPA Method 1631 instead of another approved method for mercury to be less than \$2.6 million per year. EPA believes that this rule does not impose any regulatory requirements that might significantly or uniquely affect small governments because the rule approves an additional test procedure for the measurement of mercury that might be regulated by some other action (e.g., a permit that implements a State-adopted water quality standard).

Regulatory Flexibility Analysis

Comment: The Regulatory Flexibility Act (RFA) requires description of impact of regulatory actions on small entities. EPA is incorrect in stating that the rule will not have a significant economic impact on small facilities. Commenters request that the rule be subject to OMB review and a regulatory flexibility analysis.

Response: In section VI.C. of the proposal, pursuant to section 605(b) of

the Regulatory Flexibility Act, 5 U.S.C. 605(b), the Administrator certified that this rule will not have a significant economic impact on a substantial number of small entities. This regulation approves an additional test procedure (analytical method) for the measurement of mercury which may be required in the implementation of the CWA (e.g., issuance of permits and/or establishment of WQS). EPA Method 1631 is not a *de facto* replacement for EPA Method 245.1 or any of the other existing EPA-approved methods. EPA anticipates that permit writers will only require the use of EPA Method 1631 if there is a need to assess effluents or ambient water at the low levels EPA Method 1631 can measure or after a determination that a discharge causes, has a reasonable potential to cause, or contribute to an excursion from a water quality criterion for mercury. EPA further anticipates that the incremental analytical costs that may potentially be incurred by any small entity with low mercury limits will be at most \$600 per year, assuming monthly monitoring.

4. Regulatory implications

Support for Use in Permitting

Comment: EPA should require immediate implementation of the new method and should require States to begin requiring it for NPDES compliance as soon as possible.

Response: Today's rule authorizes use of EPA Method 1631 but does not require its use for compliance monitoring or any other uses. The Agency developed EPA Method 1631 to enable reliable measurement of water samples at the levels established in water quality criteria. Consequently, EPA expects that when the measurement sensitivity of EPA Method 1631 is necessary to assess and implement water quality controls (including compliance monitoring), EPA Method 1631 will be used. If and when other methods for measuring mercury at these low levels are promulgated in 40 CFR part 136 or are approved under the procedures at 40 CFR 136.4 and 136.5, the permitting authority would have discretion to determine which method is most appropriate under the circumstances.

States that are authorized to administer the NPDES program must require use of 40 CFR part 136 methods. EPA recognizes that States may need to follow State procedures to adopt changes to 40 CFR part 136 before they can require use of a newly promulgated method and allows States a reasonable time to accomplish this. See 40 CFR 123.62(e). EPA regulations do not

require that permits be reopened to include a new analytical method. Instead, the permitting authority may have the opportunity to reopen the permit or to wait until the permit is reissued to include a new or more sensitive analytical method. See 40 CFR 122.62(a)(2).

Best Available Sensitivity

Comment: EPA failed to acknowledge that many existing permits require the permittee to use the test method with the lowest detection level.

Response: EPA recommends that EPA Method 1631 be used only for situations in which mercury may be known or thought to be the cause of an environmental or human health problem, or for investigations directed at determining whether a problem exists, in the same way that EPA recommends that other test methods be used. EPA Method 1631 is being made available for use when it is necessary to measure mercury concentrations at low levels. As previously explained, existing permit requirements to use the most sensitive method available may only incorporate the most sensitive method at the time the requirement was imposed, not methods adopted in the future.

Reporting vs. Use of Data

Comment: EPA Method 1631 states that results need not be reported for regulatory compliance purposes if the results do not satisfy QC acceptance criteria. The Inter-Industry Analytical Group (IIAG) suggests that EPA change the phrase to read: ". . . may not be reported or otherwise used for permitting or regulatory compliance purposes." IIAG also requests that EPA clarify that results from tests performed with an analytical system that is not in control also should not be reported or otherwise used for permitting or regulatory compliance purposes.

Response: EPA has adopted IIAG's suggested wording, and changed relevant text in EPA Method 1631 accordingly. The wording changes clarify the Agency's intent that data that fail to meet the Method's QC acceptance criteria are not reliable measurements of mercury.

Iodide Interference

Comment: The Inter-Industry Analytical Group (IIAG) comments that EPA fails to give adequate consideration to interferences and cites, as an example, an iodide interference problem encountered by GPU Nuclear Co. (GPU) using EPA Method 245.1. GPU attributes this interference to formation of a stable complex of iodide and mercury that

prevents reduction of mercury to its elemental form with the stannous chloride (SnCl_2) reductant. (SnCl_2 also is used in EPA Method 1631). GPU has overcome the problem by addition of a small amount of sodium tetrahydroborate to aid in reduction of mercury.

Response: EPA did not claim that EPA Method 245.1 was free from test interference. The claim was made concerning EPA Method 1631. EPA Method 1631 uses different chemistry than EPA Method 245.1. In EPA Method 1631, mercury is oxidized to Hg(II) with bromine monochloride, pre-reduced with ammonium hydroxide hydrochloride ($\text{NH}_2\text{OH}\cdot\text{HCl}$) to destroy free halogens, then reduced with SnCl_2 . The $\text{NH}_2\text{OH}\cdot\text{HCl}$ likely plays the same role as the sodium tetrahydroborate in GPU's procedure. EPA has now received a report that high concentrations of iodide ($>40 \text{ mg/L}$) can interfere in the determination of mercury using EPA Method 1631. These high concentrations can occur in in-process streams and influents, but normally would not be encountered in treated effluents. To allow for the possibility that high concentrations of iodide, however, and the possibility that other substances could interfere in the determination of mercury using EPA Method 1631, today's version of EPA Method 1631 acknowledges that test interference remain a slight possibility.

Variability and Regulatory Decisions

Comment: The Inter-Industry Analytical Group (IIAG) comments that EPA's QC acceptance criteria and other variability must be taken into account in regulatory decisions. IIAG cites the QC acceptance criteria for the matrix spike and matrix spike duplicate (MS/MSD) in EPA Method 1631 and questions EPA's rationale for determining that such a wide range of performance is acceptable, given the harsh regulatory consequences associated with excursion of permit limitations. IIAG states that EPA must explain why such variability is acceptable and how regulators are required to account for that variability in their permitting and/or compliance decisions.

Response: EPA disagrees that QC acceptance criteria are "wide." These criteria are consistent with, or narrower than, other methods for measuring pollutants at these levels (see for example the QC acceptance criteria for EPA Methods 608 and 1613 at 40 CFR part 136, appendix A). The QC acceptance criteria recognize the variability expected to occur among laboratories. The EPA developed the criteria from multiple, single-laboratory

data and verified the data in the interlaboratory study. The Agency used the laboratory data to develop the QC acceptance criteria in today's rule.

Regarding accounting for variability in permitting and compliance decisions, EPA's technology-based rules do account for analytical variability because measurement variability is a component of the overall variability encountered to develop the rule (including field measurement). Therefore, no additional allowance for analytical variability is appropriate. For water quality uses, accommodation for the effect of analytical variability is less routinized. In the Technical Support Document (TSD) for Water Quality-based Toxics Control (EPA/505/2-90-001), EPA noted that accounting for analytical variability in establishing permitting requirements can result on the one hand, in failure to be adequately protective of the wasteload allocation or, on the other hand, to be overly conservative. Therefore, EPA recommended against any additional allowance for analytical variability. However, EPA currently is developing guidance on accounting for analytical variability in permitting in the context of the whole effluent toxicity program. When finalized, that guidance may provide the basis for revising the position taken in the TSD with respect to accounting for analytical variability in general.

5. Retention of Approved Methods and Approval of Additional Methods

Support as Additional Method, With Qualification

Comment: Commenters support approval of EPA Method 1631 if it is an addition to the list of approved methods and not a replacement for existing methods, especially if a laboratory can demonstrate that it can achieve low ng/L detection limits (including needed sensitivity) with one of the presently approved methods.

Response: Today's rule approves EPA Method 1631 as an additional method that can be used when measurement of mercury at water quality criteria levels is needed. EPA doubts that a laboratory can achieve the low levels (including needed sensitivity) with one of the presently approved methods. Typically, the MDL of a method should be an order of magnitude (factor of 10) below the level desired for measurement (e.g., a regulatory compliance limit, or any water quality criterion) so that contamination can be detected and the effects of contamination evaluated. If the detection limit is at or near the level desired for measurement, it would be

difficult to determine if the presence of the substance is real or is attributable to contamination. The capabilities of EPA Method 1631 enable such an evaluation.

Support Continued Use of Approved Methods

Comment: EPA should continue to allow the use of other approved methods. Withdrawal of existing methods (EPA 245.1, 245.5, Standard Method 3112B, ASTM D3223-91, USGS I-3462-85, and AOAC-International 977.2) would be disastrous. There would be serious adverse economic ramifications if EPA Methods 245.1 and 245.2 are withdrawn. EPA Method 1631 should not be imposed on the private sector as the sole method. The option of using less sensitive methods should remain where EPA Method 1631 sensitivity is not needed.

Response: Based on comments received and the points made in those comments, today's rule allows continued use of the presently approved methods for determination of mercury when those methods achieve the desired measurement objective.

Performance-Based Measurement System

Comment: The performance-based measurement system (PBMS) as applied in proposal allows for sample preparation and trapping modifications, but does not allow for use of atomic absorption. EPA should accept application of PBMS for a different absorbance technique when it can achieve needed sensitivity.

Response: EPA proposed to implement PBMS in its water measurement programs (62 FR 14975, March 28, 1997) but has not yet promulgated a final PBMS rule. EPA anticipates that the final rule will allow use of alternate determinative techniques such as atomic absorption. Until a final rule is promulgated, however, methods approved at 40 CFR part 136 must be used according to their terms. Approval of the use of alternate procedures, such as alternate determinative techniques, can be requested through the alternate test procedure provisions described at 40 CFR 136.4 and 136.5.

6. Application to Wastewater Matrices Inapplicable to Effluent

Comment: EPA Method 1631 is not applicable to the determination of mercury in effluents. The Method should contain a statement that it is not intended for the determination of concentrations normally found in industrial discharges. Language in an earlier version of EPA Method 1631

(January 1996) stated that "this method is not intended for determination of metals at concentrations normally found in treated and untreated discharges from industrial facilities."

Response: When the Agency first began development of EPA Method 1631, the method description contained the statement that it was applicable to ambient monitoring but that it was not intended for application to industrial discharges. Since then, however, in studies of POTWs along the Great Lakes, in the interlaboratory validation study, and in other recent studies (Results of Method 1631 Application to Effluent Matrices (March 1999) and Application of Method 1631 to Industrial and Municipal Effluents (December 1998)), EPA has found that mercury could be reliably measured at low levels in municipal and industrial discharges. For this reason, and because some States requested EPA support to develop the method for measurement of municipal and industrial discharges, the Agency expanded EPA Method 1631 to cover wastewaters. The statement regarding restricted use of EPA Method 1631 was deleted from the January 1996 version.

Testing One Effluent Is Inadequate

Comment: Testing one effluent at one level by a few laboratories is not an appropriate inter-laboratory study for general NPDES application.

Response: The Agency validated EPA Method 1631 on one filtered and one unfiltered wastewater matrix in the interlaboratory validation study. Subsequently the Agency gathered additional effluent data in response to comments regarding the method's applicability to wastewaters generally. EPA made these data available in a notice of data availability on March 5, 1999 (64 FR 10596). These data demonstrate that EPA Method 1631 is applicable for measurement of municipal and industrial effluents.

7. Detection and Quantitation MDL Is Flawed

Comment: Several commenters state that Agency estimates of detection and quantitation in EPA Method 1631 are flawed. The estimates cannot be achieved in real world use. The estimates are scientifically unsound. The estimates are neither realistic nor reproducible. The estimates use an inappropriate multiplication factor. They overestimate the certainty associated with measurements. The estimates are not representative of expected performance by qualified laboratories. They are not a valid statistical basis for predicting laboratory

performance. The estimates were based on spikes into reagent water instead of wastewaters. The estimates do not consider effluent characteristics. The estimates are based on a protocol that has never been subjected to peer review and public comment. The estimates do not reflect the performance capability of laboratories that will be performing compliance monitoring.

Response: EPA disagrees that the MDLs and MLs in EPA Method 1631 were developed inappropriately. EPA Method 1631 employs the method detection limit (MDL) (see 40 CFR part 136, appendix B). The MDL is defined as the minimum concentration of a substance that can be measured and reported with 99% confidence that the analyte concentration is greater than zero and is determined from analysis of a sample in a given matrix containing the analyte. The MDL procedure is not designed to control "false positives" or "false negatives," allow for repetitive testing, or predict laboratory performance. However, since the variability of the blank is expected to be approximately equal to the variability at the MDL, measurement results greater than the MDL are unlikely to be obtained when measuring samples that do not contain the substance of interest. In effect, the MDL can be used to control the rate of "false positives." Reagent water is the matrix used for determining the MDL performance measure of a method because (1) reagent water is available to all laboratories, (2) reagent water allows determination of the lowest concentration of a substance that can be detected absent matrix interferences, and (3) there is no matrix that represents all wastewater matrices. Application of the MDL procedure to particular methods has been subject to peer review and public comment with every MDL that EPA publishes in nearly every chemical-specific method proposed in the **Federal Register** since 1984. The MDL procedure has widespread acceptance and use throughout the analytical community. No other detection or quantitation limit procedure or concept has achieved this level of acceptance and use.

EPA Method 1631 incorporates the concept of a minimum level of quantitation (ML), which is the lowest level at which an analytical system is expected to give a recognizable signal and acceptable calibration point. In 1994, EPA revised its use of the ML concept to 10 times the standard deviation associated with the MDL in order to be more consistent with the limit of quantitation (LOQ) of the American Chemical Society (ACS). The LOQ is based on a standard deviation of

replicate measurements on a blank, which is expected to be approximately equal to the standard deviation of replicate measurements at the MDL. Therefore, EPA expects the ML to be approximately equal to the LOQ. Because the MDL is established at 3.14 times the standard deviation associated with the MDL and the ML is 10 times the standard deviation associated with the MDL, the multiplier between the MDL and ML is 3.18. EPA believes that this multiplier is consistent with other multipliers selected for the purpose of quantitation and that this multiplier is therefore appropriate. Readers are referred to the response to comments document in the Docket for today's rulemaking for a more detailed response.

EPA plans to continue to examine the issues of detection and quantitation. The Agency initiated a study recently to examine the effects of error from various analytical systems on detection and quantitation, and plans to involve the public in the application of the data being gathered to develop an improved approach, if such an approach is found to exist.

Use of the MDL/ML Concepts Violate Administrative Procedure Act

Comment: Commenters opposed EPA's proposed detection and quantitation levels because EPA did not provide the opportunity for review and comment on the basis for the proposed decisions. EPA's proposal neither describes the origin of the MDL nor explains why the Agency believes that it is an acceptable basis for developing detection levels for use in compliance determinations.

Response: The MDL concept origin is an article published in the peer-reviewed scientific literature in 1981 (*Environmental Science and Technology* 15 1426-1435). The MDL procedure has been used in EPA's various environmental programs since it was published at 40 CFR Part 136, Appendix B in 1984. The MDL procedure is accepted and used by nearly all organizations making environmental measurements. Recently, EPA has undertaken data gathering that should allow re-examination of detection and quantitation limits. When this study is complete, EPA will decide if the MDL and ML continue to be appropriate or if other concepts are appropriate for EPA's scientific and regulatory purposes. EPA has involved, and will continue to involve, stakeholders in this process and in EPA's final decision. Until other detection and quantitation limit concepts are shown to be more appropriate, EPA will continue to use

the MDL and ML for the reasons stated at the beginning of this response, in other responses, and in other rules.

MDL Violates A 1985 Judicial Settlement

Comment: A commenter noted that, in a judicial settlement in 1985, EPA agreed that the MDL procedure published at 40 CFR part 136, appendix B, was intended to apply exclusively to the subset of the test methods that the Agency published at 40 CFR part 136, appendix A, in 1984. Thus, the commenter argues that, if EPA uses the MDL procedure for the purpose of deriving a detection level for EPA Method 1631, the Agency must provide the public an opportunity to review and comment on that decision. As justification for use of the MDL, EPA gave the reasons that (1) laboratories that participated in the EPA Method 1631 study were able to calculate an MDL at least as low as that achieved in an earlier study, and (2) the MDL is well below the lowest water quality criterion (WQC) in the National Toxics Rule and listed in the final water quality guidance for the Great Lakes System. The commenter argues that these reasons may be desirable but that they are irrelevant for determining an appropriate detection level. The commenter argues that EPA must first confirm that good laboratories can achieve that level.

Response: The commenter is correct that, in 1985, EPA agreed in a settlement that the MDL procedure at 40 CFR part 136, appendix B, was applicable to the 40 CFR part 136, appendix A methods only. The settlement, however, did not restrict future application of the MDL procedure, nor did it restrict any person's right to challenge the Agency's reliance on the MDL procedure in any future rulemaking. EPA provided the opportunity for comment on use of the MDL in EPA Method 1631. EPA believes that the interlaboratory validation study of EPA Method 1631 confirms that good laboratories can achieve the detection and quantitation levels that EPA established for EPA Method 1631.

Effluent Study Offers No Support for the MDL Performance Measure in EPA Method 1631

Comment: If the intent of EPA's effluent study was to determine whether MDL calculations are influenced by the sample matrix, EPA should have used a matrix more representative of real world samples rather than the City of Eugene's POTW effluent. The mercury level in the City's effluent was lower than in any

of the other effluents used in EPA's study.

Response: Step 3(b) of the MDL procedure at 40 CFR part 136, appendix B requires that the measured level of analyte be less than five times the MDL. The MDL in EPA Method 1631 is 0.2 ng/L. Five times the MDL is 1.0 ng/L and therefore the concentration of mercury in the MDL study needed to be in the range of 0.2 to 1.0 ng/L. The measured level of mercury in the City of Eugene's POTW effluent was 0.56 and 0.72 ng/L, based on data collected prior to the MDL study. Therefore, the mercury concentration of the City's sample was in the appropriate range for the MDL study.

8. Clean techniques

Clean Techniques Should Be Required

Comment: The rule should require clean sampling, handling, and analysis when EPA Method 1631 is used and the Agency should develop a comprehensive database on the level of contamination that may arise. A commenter provided a list of sections in EPA Method 1631 that allow discretion but that the commenter believes must be made mandatory to assure reliable and reproducible results, for example, if government inspectors measure the same sample effluents. The commenter argues that EPA must explain its rationale for deciding that certain clean techniques are mandatory and to justify its decision that other techniques are not mandatory and, therefore, can be left to the discretion of enforcement officials. The only exception to required use of clean techniques should be that permittees should have complete discretion as to the use of such techniques because the failure to use such techniques can only result in mercury results higher than the level actually present in an effluent.

Response: During the development of EPA Method 1631, the Agency found some researchers using very extensive measures for clean sampling, including the wearing of clean room caps, suits, booties, and shoulder-length gloves in addition to hand-length gloves. On the other hand, EPA found other researchers wearing shorts, tee shirts, and hand-length gloves only. Because the Agency sought to maximize the flexibility of capable personnel, EPA provided the Sampling Guidance (EPA Method 1669) to indicate measures to prevent and preclude contamination. The sampling guidance is not mandatory for use with EPA Method 1631 because some permittees and sampling teams are capable of reliable sample collection without the measures detailed in the guidance. The rigor of clean sample

collection techniques is determined by the required measurement objective or regulatory level (i.e., the lower the desired level, the more critical is the adherence to rigorous clean sampling protocols). Those elements of clean sampling, handling, and analysis that the Agency believes are necessary to assure reliable and reproducible results have been incorporated into EPA Method 1631. For example, the use of clean gloves by all sampling personnel and the use of metal-free apparatus are requirements specified in the method. In addition, the QC requirements in the method are designed to detect potential contamination that may arise in the field, during transport, or in the laboratory.

Regarding development of a comprehensive database, the Agency does not see the need to develop a database on the level of contamination that may arise. In both EPA Method 1631 and the Sampling Guidance (EPA Method 1669), EPA is very explicit that contamination is a concern and, consequently, the Agency provided appropriate measures to minimize contamination.

EPA includes a number of mandatory steps in a method when it believes those steps are necessary to provide reliable analytical results. If EPA were to justify every discretionary aspect of a method (indicated by the words "should," or "may," and other words denoting suggestions) for every method or guidance document that the Agency develops, method and document development would grind to a halt. Parametric studies of every variable that could possibly influence the outcome of a method or use of a document would become cost-prohibitive. The list of discretionary techniques in EPA Method 1631 that the commenter suggests should be evaluated would require 20 parametric studies.

Clean Techniques Should Not Be Required

Comment: Clean techniques should not be required. There is no documentation in the record that clean field blanks and clean samples can be collected. This casts doubt on the ability of laboratories and permittees to use this method in day-to-day activities designed to meet Clean Water Act requirements. Clean techniques are an unnecessary expense because detection levels this low are not needed for personal or environmental protection. EPA Method 1631 is able to detect such low levels that sample collection and analysis must occur in pristine environments to prevent false positives.

Response: Clean techniques are not required but are recommended for low level mercury measurements associated with WQ criteria. EPA cautions, however, that contamination has been identified as a potential problem in collecting samples for mercury prior to the advent of clean techniques. Use of these techniques, as detailed in the sampling guidance (EPA Method 1669) and in the technical literature (see references 2-9 of EPA Method 1631), has allowed collection of samples free of contamination at ng/L levels. EPA urges use of clean techniques, as appropriate, to preclude contamination. As stated earlier, those elements of clean sampling, handling, and analysis that the Agency believes are necessary to assure reliable and reproducible results have been incorporated into EPA Method 1631.

Although EPA agrees that clean techniques should not be (and are not) required, EPA disagrees with the commenters assertion that the record contains no documentation that clean field blanks and clean samples can be collected. The EPA Method 1631 Interlaboratory Study included the collection of field samples for use in the study, and results from background and QC analyses demonstrated the ability to collect clean field blanks and samples. Following proposal of the method, EPA also collected additional effluent data and made those data, including QC results, available in the Docket and through a notice of data availability (64 FR 10596). These data provide further demonstration that clean field blanks and clean samples can be collected.

9. Corrections to statements in proposal Holding Time

Comment: Proposed EPA Method 1631 lists a holding time of 6 months. EPA used a period of only one month, however, to evaluate the stability of the samples. Please provide the basis for the large variation in holding times between EPA Method 1631 (6 months), EPA Method 245.1 (28 days), and draft EPA Method 245.7 (72 hours). EPA must have data to support the specified maximum holding time and will need to change holding time in CFR if EPA Method 1631 is approved.

Response: EPA specified the maximum holding time at 6 months in the proposed version of EPA Method 1631 based on statements by a number of laboratories involved in development of EPA Method 1631 that samples could be held for this period. EPA requested data that would support the 6 month holding time. Data were not forthcoming. Therefore, in today's

version of Method 1631, EPA has specified a maximum holding time of 28 days, consistent with Table II at 40 CFR part 136.

Lowest Water Quality Criterion

Comment: The lowest water quality criterion (WQC) for the Great Lakes Water Quality Guidance is not 1.8 ng/L. It is 1.3 ng/L, the criterion for wildlife protection (see Table 4 to 40 CFR part 132). Waters of the United States frequently exceed these levels even where there is no direct industrial or municipal discharge.

Response: EPA stands corrected. EPA recognizes that waters of the United States can exceed Great Lakes WQC levels, even where there is no industrial or municipal discharge. That possibility, however, does not affect the substance of today's rule.

10. Quality Control

Excessive quality Control

Comment: The quality control (QC) in EPA Method 1631 is excessive, unreasonable, far more rigorous than in currently approved methods, and demonstrates the inappropriateness of this method for general application.

Response: The QC in EPA Method 1631 is consistent with the other 40 CFR part 136, appendix A methods and consistent with requirements for other environmental analytical chemistry methods. EPA believes that the QC requirements are necessary to ensure the reliability of data results and that these requirements are not onerous.

Insufficient Quality Control

Comment: Without addition of more comprehensive QC for background, mercury determinations at low ppt levels are subject to unknown and unacceptable bias and imprecision. Additional validation and modification to the QA/QC are necessary for the method to realize its potential of being a rugged method capable of providing reliable quantification of mercury at sub-ng/L concentrations.

Response: Bubbler blanks, reagent blanks, and method blanks serve as checks on contamination. The MDL performance capacity of Method 1631 is 0.2 ng/L. This MDL enables detection of contamination at sub-ng/L concentrations, should such contamination occur. A discharger or laboratory is not precluded from performing additional QC if it desires.

Method Performance

Comment: A commenter argues that EPA must assure that the irreducible performance limitations inherent in all methods will not act to penalize persons

for lawful conduct. EPA cannot provide such assurances absent adequate performance data, which can only be derived from properly conducted method validation studies. If EPA determines that a test method has been adequately validated, EPA must publish performance characteristics along with the method.

Response: EPA conducted a validation study on EPA Method 1631. Published method performance characteristics associated with the Method include: (1) A method detection limit (MDL) and minimum level of quantitation (ML) in Table 1, (2) quality control (QC) acceptance criteria in Table 2, and (3) precision and recovery data for six sample types in Table 3. These data more than adequately support the adequacy of the Agency's validation of EPA Method 1631.

11. Blanks and Contamination

Reagent Blanks

Comment: Reagent blanks also should be subtracted from sampling results. Otherwise, inaccurate, high results will be reported.

Response: Section 12.4 in EPA Method 1631 asks for separate reporting of results for samples and blanks, unless otherwise requested or required by a regulatory authority or in a permit. The reason for separate reporting is so that a regulatory authority can assess if results for samples are attributable to contamination and the extent to which contamination is affecting the measurement. There is no prohibition in EPA Method 1631 against reporting blank-subtracted results, provided, of course that results for blanks and samples are reported separately.

Bubbler and Reagent Blanks Inadequate

Comment: Bubbler blanks and reagent blanks only demonstrate that the analytical system is uncontaminated. Analysis of field or equipment blanks should not be used to demonstrate laboratory capabilities.

Response: EPA agrees that bubbler blanks and reagent blanks are used to demonstrate that the analytical system is uncontaminated. EPA disagrees that field blanks or equipment blanks should not be used to demonstrate laboratory capabilities. The laboratory is responsible for determining and reporting field contamination and for demonstrating that equipment blanks are free from contamination. Section 9.4 of EPA Method 1631 also contains a statement "it is suggested that additional blanks be analyzed as necessary to pinpoint sources of contamination in, and external to, the

laboratory." Both field and laboratory contamination sources may affect the analytical results.

Blank Subtraction

Comment: It should be acceptable to subtract field blank results in addition to reagent and bubbler blanks. EPA must require correction for reagent blanks.

Response: EPA has revised section 12.4 of the method to ask for reporting the concentration of mercury in field blanks but has not required blank subtraction so that a regulatory authority can assess if results for samples are attributable to contamination and the extent to which contamination is affecting the measurement. A regulatory authority or other data user may subtract the concentration of mercury in field blanks or reagent blanks if it believes this subtraction is appropriate. Today's rule does not preclude the reporting of blank-subtracted results provided that results for samples and blanks are reported separately.

Sample-Specific Reagent Concentrations

Comment: The reagent blank does not address sample-specific variation in reagent concentrations. Section 11.1.1.2 states that sewage effluent will require high levels of bromine monochloride (BrCl). The increased requirement for BrCl for samples high in organic materials could increase the background contribution if the BrCl contains trace amounts of mercury. This could lead to a high bias for mercury in samples that require high levels of BrCl. EPA Method 1631 states that BrCl cannot be purified (section 9.4.2.3).

Response: EPA agrees and has added the requirement that whatever concentration or amount of reagent that is added to the sample must also be added to the reagent blank in order to identify the reagent as a potential source of contamination. Regarding the statement in EPA Method 1631 that BrCl cannot be purified, EPA believes that this statement is true. BrCl, however, is made in the laboratory from several reagents that can be obtained in highly purified form. The resulting BrCl will then be very pure.

12. Validation Study

Insufficient Validation

Comment: Insufficient method validation has been provided to justify method use for routine NPDES purposes.

Response: The validation steps performed with EPA Method 1631 are

the same as EPA has performed with many other methods. The Agency validated EPA Method 1631 first in multiple single-laboratory studies and then further validated the method in an interlaboratory study. EPA followed ASTM Practice D 2777 in the interlaboratory validation study design. Some members of the ASTM Committee D-19 on water reviewed the interlaboratory study plan and contributed to the study. In response to commenters concerned about the application of EPA Method 1631 to NPDES effluents, EPA gathered data on application of EPA Method 1631 to effluents and made these data available to commenters for review prior to today's final rule (64 FR 10596).

Validation Under Routine Conditions

Comment: Validation data results were not obtained under normal, routine analytical operations. EPA Method 1631 should not be promulgated until it is validated using commercial laboratories able to sample and analyze waste streams using ultra-clean techniques. The fact that EPA Method 1631 has been subjected to the required validation studies alone does not ensure that it is ready for widespread application.

Response: Commercial laboratories were included in the interlaboratory method validation study and all laboratories involved in the study perform mercury analyses routinely using the techniques in EPA Method 1631. It is not necessary for commercial laboratories involved in the analysis of samples for mercury to be able to sample waste streams, although some do. All laboratories involved in the interlaboratory study analyze waste streams and all of the laboratories involved in the study determined their respective detection limits. EPA believes that the fact that EPA Method 1631 has been subjected to the required validation ensures that it is ready for widespread application. Over time, commercial laboratories will develop capacity to conduct EPA Method 1631 just as they have for other, previously approved test methods.

Additional Interlaboratory Studies

Comment: EPA's intralaboratory (i.e., within laboratory) studies reported in the Docket with the NODA failed to evaluate the matrix issue in a "real-world" interlaboratory context. EPA did not assess interlaboratory precision and bias in studies included with the NODA. EPA's data are insufficient to characterize precision and bias of mercury measurements in industrial effluents. Although the study included

analysis of mercury samples by multiple laboratories, none of the samples was split between laboratories. The studies should have been designed to determine interlaboratory and multi-matrix precision, accuracy, and sensitivity of EPA Method 1631.

Response: Assessing interlaboratory precision and bias was not an objective of the additional studies. EPA assessed interlaboratory precision in the interlaboratory validation study and published performance data for the interlaboratory validation study in the report that was included in the Docket at proposal. In comments on EPA's proposal of EPA Method 1631 on May 26, 1998 (63 FR 28867), commenters expressed concern that only one municipal secondary effluent had been analyzed to determine precision and bias and that no industrial wastewater samples were analyzed. They argued that it was unreasonable for EPA to adopt a method with no data on the applicability to a wide variety of wastewater matrices. In response to those concerns, the Agency applied EPA Method 1631 to a wide variety of wastewater matrices, including industrial wastewater samples. EPA gathered data generated from the analyses of several different types of effluent samples in order to determine whether the results from that study meet the quality control (QC) acceptance criteria from the proposed method. EPA developed the QC acceptance criteria as a means of assuring the appropriate levels of precision and bias. Re-evaluation of precision and bias would be unnecessary if the QC acceptance criteria remained appropriate.

The commenters claim that EPA Method 1631 was validated inadequately because EPA did not conduct interlaboratory method validation studies on a wide variety of wastewater matrices containing naturally occurring mercury levels near the ML of EPA Method 1631. EPA disagrees. The ASTM guidelines recommend the use of reagent water as a reference matrix in at least one environmental sample matrix other than the reference matrix. EPA included a municipal effluent in the interlaboratory validation study. It would be impractical to use a wide variety of wastewater matrices with natural concentration near the ML of EPA Method 1631 because the levels in the sample are unknown prior to analysis. EPA followed ASTM and AOAC guidelines for the interlaboratory method validation study conducted prior to proposal. EPA believes that the Agency has fully addressed commenters' requests for additional

data on the application of EPA Method 1631 to wastewaters. Commenters that have requested that EPA conduct extensive interlaboratory studies were involved in, and had the opportunity to contribute to, EPA's interlaboratory method validation study at the time it was conducted. These commenters chose not to contribute to a more extensive study or conduct studies on their own.

EPA reiterates that the main objective in conducting the additional studies was to demonstrate that effluent samples containing mercury at or near the ambient water quality criteria levels given in the National Toxics Rule (40 CFR 131.36) and in the Water Quality Guidance for the Great Lakes System (40 CFR part 132) could be analyzed with little or no difficulty. Data included in the Docket with the NODA and data provided by the State of Maine demonstrate that these measurements can be made reliably, claims from commenters about interlaboratory variability, precision, accuracy, and sensitivity notwithstanding.

Insufficient Concentrations

Comment: A commenter argued that EPA failed to validate EPA Method 1631 at a sufficient number of concentrations. The commenter cites a report prepared by the Electric Power Research Institute (EPRI) in which consultants to EPRI cite ASTM Practice D 2777-96 as the need to validate the method using samples spiked at multiple levels.

Response: EPRI and EPA collaborated on the study design for the EPA Method 1631 interlaboratory validation study. EPA shared data from the study with EPRI's consultants immediately after these data were verified and validated. The consultants acknowledge the collaboration in the attachment to the comment. At the outset of the study, EPA and EPRI agreed on the limitations of the study, including that there were insufficient resources to test every matrix at multiple levels. In the study, EPA validated EPA Method 1631 at multiple levels in reagent water and in freshwater collected near Port Washington, Wisconsin. To support today's final rule, EPA has gathered additional data on a variety of complex effluents using EPA Method 1631 and evaluated them at the low concentration levels of interest (i.e., low parts per trillion). These data represent the application of the Method to "real world" effluent samples. The data results demonstrate that Method 1631 can be successfully applied to effluents because all of the matrix spike and

matrix spike duplicate (MS/MSD) recoveries were within the QC acceptance criteria in EPA Method 1631, with the exception of two samples that were spiked at inappropriate levels.

EPA Did Not Follow Voluntary Consensus Standards Bodies (VCSB) Procedures

Comment: A commenter claims that EPA failed to use available standards and practices from VCSBs to design its method validation study as required by the National Technology Transfer and Advancement Act (NTTAA) and Office of Management and Budget (OMB) Circular A-119. The commenter asserts that NTTAA makes no distinction between technical standards that are themselves scientific tests (i.e., analytical methods) and standards used in the evaluation of the effectiveness and reliability (i.e., validation) of those tests. The commenter states that EPA claims to have complied with NTTAA by developing a new mercury method that had not yet been developed by a VCSB and that EPA incorrectly claims to have followed VCSB standards for the design and conduct of its validation study.

Response: EPA agrees that NTTAA and OMB Circular A-119 require federal agencies to consider available VCSB standards and practices. NTTAA requires federal agencies to consult with VCSBs and other organizations when such participation is in the public interest and is compatible with agency missions, authorities, priorities, and budget resources. If compliance with the requirement to use VCSB standards and practices is inconsistent with applicable law or otherwise impractical, a federal agency may elect to develop technical standards not developed or adopted by VCSBs if the head of the agency or department transmits to OMB an explanation of the reasons for using other standards.

EPA disagrees with the commenter's statement that we failed to use available standards and practices from VCSBs to design its method validation study. EPA designed the interlaboratory study with participation by the Electric Power Research Institute (EPRI) and its consultants. Individuals in EPRI are members of ASTM Committee D-19 on water. Committee D-19 developed Practice D 2777. The Agency followed Practice D 2777 in the study design. Practice D 2777 requires the use of at least one representative ("reference") sample matrix which is the same for all laboratories and recommends the use of at least one environmental sample matrix. Reagent water is recommended as the reference sample matrix. In a

memorandum attached to the comment, the only statement suggesting that EPA did not follow Practice D 2777 in the study design is a statement that Practice D 2777 requires Youden pairs at a minimum of three concentrations per matrix. EPA included four concentration pairs in reagent water (and an unspiked pair), four concentration pairs for freshwater, and one concentration pair each for marine (one pair filtered and one pair unfiltered) and for a municipal effluent (one pair filtered and one pair unfiltered). EPA believes that the design of its validation study follows ASTM Practice 2777-96. EPRI members were aware of the resource limitations of the study and agreed that the design's limited number of Youden pairs and blind duplicate samples would not negate the usefulness of study results.

Performance Data Are Inadequate and Misleading

Comment: A commenter argues that EPA's performance information is inadequate and misleading because it fails to include regression equations. Stakeholders need a means to predict how EPA Method 1631 will perform at any particular level within its working range. EPA has provided regression equations in other methods. EPA inexplicably departed from this practice. The commenter further argues that EPA's performance information is inadequate and misleading because the EPA Method 1631 acceptance criteria are inconsistent with study results. For example, test data can be used if the initial precision and recovery falls within the range of 79-121 percent which is broader than the capability (86-113 percent) demonstrated by the EPA Method 1631 interlaboratory study. EPA must explain the difference in the final rule, if only to avoid confusion in the interpretation of EPA Method 1631 data.

Response: EPA disagrees that the performance information is inadequate and misleading. As EPA has stated elsewhere in these responses, EPA has no knowledge of use of regression equations in the interpretation of data by dischargers or others. Regression equations are redundant with QC acceptance criteria. Regression equations can be used to calculate expected method performance at a given concentration. The expected performance can, in turn, be used to determine if a laboratory's performance is equivalent to the performance of laboratories in the interlaboratory study. On the other hand, laboratories that practice a method that contains QC acceptance criteria recognize these

criteria as absolute standards of performance within which the method must operate. Calculating another standard of performance, as the commenter suggests, would be redundant. Further, because the QC acceptance criteria are an absolute standard, laboratories can be held accountable. If they fail to meet this standard, corrective action would be required followed by reanalysis of samples after the QC acceptance criteria are met. Standards of performance derived from regression equations do not ensure this result.

The difference between the QC acceptance criteria listed in proposed EPA Method 1631 and in Table 11 of the interlaboratory study report are attributable to EPA's decision to not tighten the acceptance criteria from the draft method published in 1995 (EPA 821-R-96-027). EPA is concerned that any method that is iteratively tested may result in ever tightening QC acceptance criteria because succeeding data gathered with the method will likely fall within these criteria. EPA therefore retained the QC acceptance criteria from the draft method in the version of EPA Method 1631 proposed. In contrast, EPA has widened the QC acceptance criteria for the matrix spike and matrix spike duplicate (MS/MSD) between the proposed version and today's version. The reason for this widening is that the data gathered in the interlaboratory study demonstrated that the QC acceptance criteria for the MS/MSD were too restrictive. Making certain QC acceptance criteria unreasonably restrictive is onerous upon laboratories, especially new laboratories beginning to practice a method. Therefore, for EPA Method 1631, the Agency decided not to tighten the QC acceptance criteria for the IPR and OPR, and loosened the QC acceptance criteria for the MS/MSD.

Mercury Forms and Species

Comment: Mercury exists in many forms and states. The interlaboratory validation study failed to consider molecular diversity of mercury.

Response: EPA Method 1631 determines total mercury. The oxidation step in EPA Method 1631 oxidizes all commonly occurring forms and species to Hg(II) which is subsequently reduced to volatile Hg(0) so that it can be purged from solution and determined.

13. Technical details of EPA Method 1631

UV Oxidation

Comment: EPA must study and validate EPA Method 1631 with UV

oxidation on a range of industrial effluents and sewage samples, including "microbially-rich" samples. Results of the commenters' studies suggest that UV photo-oxidation can increase recoveries in some effluents. The use of UV oxidation makes measurement of mercury method-defined.

Response: In section 3.1 of EPA Method 1631, the Agency suggests use of UV oxidation for microbially-rich samples. EPA has added recommendations for determining complete oxidation. These recommendations should aid in recovery of mercury from some samples, as the commenter suggests. Regarding all interferences not being oxidizable, the commenter provided no example of a non-oxidizable interference that could occur in wastewaters.

Regarding the use of UV oxidation making mercury a "method-defined analyte," mercury could become method-defined in EPA Method 1631 only if it were not recovered reliably from a large number of samples. For the few number of samples in which incomplete oxidation can occur to make consideration of mercury as "method-defined," the additional recommendations should now assure complete oxidation so that mercury does not need to be considered "method-defined." Total mercury can be determined reliably.

Safety

Comment: There are safety hazards inherent in the practice of EPA Method 1631. The preparation of bromine monochloride (BrCl) is more hazardous than preparation of potassium permanganate (KmnO4). A significant amount of hot acid is involved in cleaning bottles/glassware. Laboratory ovens will be destroyed or serve as a source of contamination as a result of cleaning bottles that need to sit overnight at 60–70 °C with HCl. Further clarification and explanation is requested on what is required for laboratory personal hygiene monitoring.

Response: Section 5 of EPA Method 1631 is dedicated to safety issues, and the sampling guidance (EPA Method 1669) contains additional information on safety. Section 7.6 of EPA Method 1631 explicitly states that BrCl must be prepared under a hood because copious quantities of free halogens are generated. The sampling guidance contains detailed procedures for bottle cleaning including suggestions for a heated acid vat in which bottles may be cleaned. Use of metal ovens for heating acids is not suggested for the reason that the commenter states. EPA Method 1631 is performance-based, however, and

allows laboratories to modify the cleaning protocols so long as the modified protocols are capable of yielding uncontaminated equipment blanks.

Regarding personal hygiene monitoring, EPA has added the statement to EPA Method 1631 to recommend that the personal hygiene monitoring be performed using Occupational Safety and Health Administration (OSHA) or National Institute of Occupational Safety and Health (NIOSH) approved personal hygiene monitoring methods.

14. Miscellaneous

Toxicity Limit

Comment: The fact that EPA has established toxicity limits at extremely low levels by a means not based on laboratory analyses does not mean that analytical technology can be developed.

Response: EPA believes that ambient water quality criteria and health effects-based limits can best be supported by gathering of data at levels represented by these criteria and limits, the means for establishing these limits notwithstanding. EPA will continue to strive to develop the analytical technology that will allow reliable measurements at these levels.

Dissolved Mercury Only

Comment: EPA should clarify that EPA Method 1631 applies to dissolved mercury only. If the total digestion is performed, naturally occurring sediments may contribute significant analyte concentrations to a result.

Response: Today's rule approves use of EPA Method 1631 for determination of dissolved and total mercury. If a sample contains suspended material such as sediment, it is intended that the mercury attached to or contained in the sediment be included in the measurement.

Ambient Criterion Based on Methyl Mercury

Comment: The ambient water quality criterion of 12 ng/L for mercury is based on methyl mercury. EPA incorrectly implied in the proposal that EPA Method 1631 should be used to show compliance with the methyl mercury-based 12 ng/L standard, and should remove reference to this standard if the method is finalized.

Response: The criterion continuous concentration (CCC) of 12 ng/L is for total recoverable mercury in water (40 CFR 131.36(b)(1)). Today's rule approves EPA Method 1631 so that reliable measurements of mercury can be made at this level, the basis for the standard notwithstanding. Both "total"

and "dissolved" mercury measurements can be made with this method.

Grab Samples

Comment: The commenter requests that EPA provide a note in 40 CFR Part 136 that requires only grab samples should be collected when using EPA Method 1631 because of potential contamination with compositing sampling procedures.

Response: EPA has not mandated use of grab samples because EPA does not wish to discourage use of automated compositing equipment or sampling by other means, although EPA cautions that precluding contamination using these methods is more difficult than with collection of grab samples.

Implementation

Comment: A commenter argues that the rulemaking for EPA Method 1631 also must provide an objective and clear description regarding how the Method is to be implemented in practice.

Response: The meaning of the comment is unclear. If the commenter means that the details of EPA Method 1631 are inadequate and the procedures in EPA Method 1631 need to be developed further, EPA believes that the validation study demonstrates that the procedures in EPA Method 1631 are more than adequate for implementation of EPA Method 1631 in practice.

If the commenter means that EPA must examine the impact of the measurements made by the method on the regulatory process, EPA believes that this activity is outside the scope of method development, validation, and approval. EPA's regulations for water pollution control are based on wastewater treatment and water quality considerations as required by the Clean Water Act. EPA Method 1631 is simply a tool to measure total mercury in aqueous samples.

Personnel Qualifications

Comment: A commenter argues that EPA should specify the minimum qualifications for persons performing EPA Method 1631. Section 4.3.2 of EPA Method 1631 states that it is imperative that the procedures be carried out by well-trained, experienced personnel.

Response: Section 1.10 states that EPA Method 1631 "should be used only by analysts who are experienced in the use of CVAFS techniques and who are trained thoroughly in the sample handling and instrumental techniques described in this Method. Each analyst who uses this Method must demonstrate the ability to generate acceptable results using the procedure in section 9.2."

VI. Regulatory Requirements

A. Executive Order 12866

Under Executive Order 12866 (58 FR 51735, October 4, 1993), the Agency must determine whether a regulatory action is "significant" and therefore subject to OMB review and the requirements of the Executive Order. The Order defines "significant regulatory action" as one that is likely to result in a rule that may: (1) Have an annual effect on the economy of \$100 million or more or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities; (2) create a serious inconsistency or otherwise interfere with an action taken or planned by another agency; (3) materially alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in the Executive Order."

Pursuant to the terms of Executive Order 12866, it has been determined that this rule is a "significant regulatory action." As such, this action was submitted to OMB for review. OMB made no suggestions or recommendations on this rule.

B. Unfunded Mandates Reform Act

Title II of the Unfunded Mandates Reform Act of 1995 (UMRA), Pub. L. 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 significantly or uniquely may affect small governments, including tribal governments, it must have developed under section 203 of UMRA, a small government agency plan. The plan must provide for 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 final rule does not contain a federal mandate (under the regulatory provisions of Title II of the UMRA) for State, local, or tribal governments or the private sector that may result in expenditures of \$100 million or more in any one year. EPA has determined that this rule contains no regulatory requirements that significantly or uniquely might affect small governments. As discussed below under the Regulatory Flexibility Act, the economic impact on small entities is anticipated to be small. This rule makes available a testing procedure which would be used at the discretion of the permitting authority when compliance with State-adopted water quality standards necessitates a more sensitive method than those previously approved. This rule would impose no enforceable duty on any state, local or tribal governments or the private sector, nor would it significantly or uniquely affect them. It would not significantly affect them because any incremental costs incurred are small and it would not uniquely affect them because it would affect all size entities based on whether testing for mercury is otherwise required by a regulatory authority. Further, monitoring for small entities is generally expected to be less frequent than monitoring for larger entities. Therefore, today's rule is not subject to the requirements of sections 202, 203 and 205 of UMRA.

C. Regulatory Flexibility Act

Under the Regulatory Flexibility Act (RFA), 5 U.S.C. 601 *et seq.*, as amended by the Small Business Regulatory Enforcement Fairness Act (SBREFA), EPA generally is required to conduct a regulatory flexibility analysis describing the impact of the regulatory action on small entities as part of rulemaking. However, under section 605(b) of the RFA, if EPA certifies that the rule will not have a significant economic impact on a substantial number of small

entities, EPA is not required to prepare a regulatory flexibility analysis. Pursuant to section 605(b) of the Regulatory Flexibility Act, 5 U.S.C. 605(b), the Administrator certifies that this rule will not have a significant economic impact on a substantial number of small entities.

This regulation approves a testing procedure for the measurement of mercury which EPA anticipates will be used by regulatory authorities when a permit limit has been set below the level of detection of previously approved methods. In developing this regulation, EPA considered the effects on small entities. Section 601(6) of the RFA defines small entity as small business, small governmental jurisdiction, and small organization. The small entities that might be affected by this rule include small governmental jurisdictions (that own POTWs) and small businesses with discharge permits for mercury at or below 200 ng/L. Of the 477 entities that we have identified with mercury limits at or below 200 ng/L, 143 are businesses, 38 are drinking water treatment plants in Puerto Rico, and 296 are POTWs.

To evaluate the potential impact on small businesses, EPA first assumed that all of the 143 businesses were small. EPA assigned to each identified facility the approximate average revenue for a small business in the SIC code to which that facility belongs. If the facility is classified as a "major" discharger in the Permit Compliance System (PCS), EPA assumed incremental analytical monitoring costs of \$5,200 per year. This assumption is based upon weekly monitoring for mercury at two sample locations using Method 1631, and assumes each facility will incur an incremental cost of \$50 per sample (the high end of the range of incremental costs). If the facility is classified as a "minor" discharger in PCS, EPA assumed incremental analytical monitoring costs of \$600 per year. This assumption is based upon monthly monitoring for mercury at one sample location using Method 1631, and again assumes each facility will incur the high end incremental cost of \$50 per sample. EPA then calculated the ratio of costs (using these upper-bound assumptions) to the assigned revenue to derive an upper-bound estimate of the impacts. The ratio is above 0.5 percent for only three facilities—"major" facilities, which may not be small businesses—and in all cases is below 4 percent. On average, the impacts were much lower. Specifically, the mean ratio for all of the facilities is 0.17 percent and the median ratio is 0.06 percent. Although PCS contains limitations data for over 20

percent of the "minor" dischargers, EPA believes that "minor" dischargers without limitations data in PCS would have a similarly low level of impact. No "minor" discharger is expected to experience an impact of more than 0.5 percent of revenues.

Small governments are those representing jurisdictions of less than 50,000 people. The 38 drinking water plants in Puerto Rico are state-owned and thus are not small governments. To evaluate the impact on small POTWs, EPA looked at the potential impacts on two sizes of POTWs to represent both "major" and "minor" dischargers potentially affected by the regulation. Based on national estimates from the Census of Governments, local governments collect \$79.31 per person in sewerage charges, which EPA assumed to be the average per capita revenue for POTWs from the population that they serve. On average, a POTW has a flow of 100 gallons per day for each person that it serves. EPA assumed that a POTW serving 1,000 people (having a flow of 100,000 gallons per day) would have revenues of \$79,310 and incur costs of \$600 (using the same assumptions as for "minor" businesses), which is 0.76 percent of its revenue. Similarly, EPA estimated that a POTW serving 10,000 people (having a flow of 1 million gallons per day, and thus being a major discharger) would have revenue of \$793,100 and incur costs of \$5,200 (using the same assumptions as for "major" businesses), which is only 0.66 percent of revenue.

Based upon these estimates, EPA concludes that this rule will not have a significant economic impact on a substantial number of small entities.

D. Paperwork Reduction Act

This rule contains no information collection requirements. Therefore, no information collection request has been submitted to the Office of Management and Budget (OMB) for review and approval under the Paperwork Reduction Act of 1995, 44 U.S.C. 3501 *et seq.*

E. Submission to Congress and the General Accounting Office

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 July 8, 1999.

F. 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), Pub. L. 104-113, section 12(d) (15 U.S.C. 272 note) directs EPA to use voluntary consensus standards in its regulatory activities unless to do so would be inconsistent with applicable law or otherwise impractical. Voluntary consensus standards are technical standards (e.g., materials specifications, test methods, sampling procedures, business practices) that are developed or adopted by voluntary consensus standards bodies. The NTTAA directs EPA to provide Congress, through the Office of Management and Budget (OMB), explanations when the Agency decides not to use available and applicable voluntary consensus standards. This rulemaking involves technical standards. Therefore, the Agency conducted a search to identify potentially applicable voluntary consensus standards. EPA's search of the technical literature revealed that there are no consensus methods for determination of mercury at these trace levels, although the American Society of Testing and Materials (ASTM) potentially is in the process of developing an analytical method for the determination of trace levels of mercury. If ASTM or another voluntary consensus standard body approves such a method and EPA believes that the method is suitable for compliance monitoring and other purposes, EPA will promulgate the method in a subsequent rule. As mentioned earlier, the Agency followed ASTM's Practice D 2777 (a voluntary consensus standard) in the design of EPA's interlaboratory method validation study for EPA Method 1631.

G. Executive Order 13045

Executive Order 13045, "Protection of Children from Environmental Health Risks and Safety Risks," (62 FR 19885, April 23, 1997) applies to any rule that: (1) Is determined to be "economically significant" as defined under E.O. 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. EPA interprets E.O. 13045 as applying only to those regulatory actions that are based on health or safety risks, such that the analysis required under section 5-501 of the Order has the potential to influence the regulation. Although it has been determined that this rule is a "significant regulatory action" under E.O. 12866, it is not economically significant and, therefore, E.O. 13045 does not apply. In addition, this rule does not establish an environmental standard intended to mitigate health or safety risks.

H. Executive Order 12875

Under Executive Order 12875, "Enhancing the Intergovernmental Partnership," EPA may not issue a regulation that is not required by statute and that creates a mandate upon a State, local or tribal government, unless the Federal government provides the funds necessary to pay the direct compliance costs incurred by those governments, or EPA consults with those governments. If EPA complies by consulting, E.O. 12875 requires EPA to provide to the Office of Management and Budget a description of the extent of EPA's prior consultation with representatives of affected State, local and tribal governments, the nature of their concerns, any written communications from the governments, and a statement supporting the need to issue the regulation. In addition, Executive Order 12875 requires EPA to develop an effective process permitting elected officials and other representatives of State, local and tribal governments "to provide meaningful and timely input in the development of regulatory proposals containing significant unfunded mandates."

Today's rule does not create a mandate on State, local or tribal governments. States have been particularly supportive of EPA's efforts to approve a more sensitive test method for mercury. The rule does not impose any enforceable duties on these entities. This rule makes available a testing procedure for use when testing is otherwise required by a regulatory agency. Accordingly, the requirements of section 1(a) of Executive Order 12875 do not apply to this rule.

I. Executive Order 13084

Under Executive Order 13084, "Consultation and Coordination with Indian Tribal Governments," EPA may

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

regulatory policies on matters that significantly or uniquely affect their communities."

As described under the Regulatory Flexibility Analysis, today's rule does not significantly or uniquely affect the communities of Indian tribal governments. Further, this rule does not impose substantial direct compliance costs on Tribal governments. This rule makes available a testing procedure which would be used when testing is otherwise required by a regulatory agency to demonstrate compliance with water quality-based permit limits for mercury. Accordingly, the requirements of section 3(b) of Executive Order 13084 do not apply to this rule.

List of Subjects in 40 CFR Part 136

Environmental protection, Analytical methods, Incorporation by reference, Monitoring, Reporting and recordkeeping requirements, Waste treatment and disposal, Water pollution control.

Dated: May 28, 1999.

Carol M. Browner,
Administrator.

In consideration of the preceding, USEPA amends 40 Code of Federal Regulations part 136 as follows:

PART 136—GUIDELINES ESTABLISHING TEST PROCEDURES FOR THE ANALYSIS OF POLLUTANTS

1. The authority citation of 40 CFR part 136 continues to read as follows:

Authority: Secs. 301, 304(h), 307, and 501(a), Pub. L. 95-217, Stat. 1566, *et seq.* (33 U.S.C. 1251, *et seq.*) (The Federal Water Pollution Control Act Amendments of 1972 as amended by the Clean Water Act of 1977).

2. Section 136.3, paragraph (a), Table IB.—List of Approved Inorganic Test Procedures, is amended by revising entry 35 to read as follows:

§ 136.3 Identification of test procedures.

(a) * * *
* * * * *

TABLE IB—LIST OF APPROVED INORGANIC TEST PROCEDURES

Parameter, units and method	Reference (method number or page)				
	EPA 1,35	STD methods 18th ed.	ASTM	USGS 2	Other
* * *	*	*	*	*	*
35. Mercury—Total, 4 mg/L:					
Cold vapor, manual, or	245.1	3112 B	D3223-91	I-3462-85	3 977.22
Automated	245.2
Oxidation, purge and trap, and cold vapor atomic fluorescence spectrometry (ng/L).	43 1631
* * *	*	*	*	*	*

Table 1B Notes:

¹ "Methods for Chemical Analysis of Water and Wastes," Environmental Protection Agency, Environmental Monitoring Systems Laboratory—Cincinnati (EMSL-CI), EPA-600/4-79-020, Revised March 1983 and 1979 where applicable.

² Fishman, M.J., et al. "Methods for Analysis of Inorganic Substances in Water and Fluvial Sediments", U.S. Department of the Interior, Techniques of Water—Resource Investigations of the U.S. Geological Survey, Denver, CO, Revised 1989, unless otherwise stated.

³ "Official Methods of Analysis of the Association of Official Analytical Chemists," methods manual, 15th ed. (1990).

⁴ For the determination of total metals the sample is not filtered before processing. A digestion procedure is required to solubilize suspended material and to destroy possible organic-metal complexes. Two digestion procedures are given in "Methods for Chemical Analysis of Water and Wastes, 1979 and 1983." One (Section 4.1.3), is a vigorous digestion using nitric acid. A less vigorous digestion using nitric and hydrochloric acids (Section 4.1.4) is preferred; however, the analyst should be cautioned that this mild digestion may not suffice for all sample types. Particularly, if a colorimetric procedure is to be employed, it is necessary to ensure that all organo-metallic bonds be broken so that the metal is in a reactive state. In those situations, the vigorous digestion is to be preferred making certain that at no time does the sample go to dryness. Samples containing large amounts of organic materials may also benefit by this vigorous digestion, however, vigorous digestion with concentrated nitric acid will convert antimony and tin to insoluble oxides and render them unavailable for analysis. Use of ICP/AES as well as determinations for certain elements such as antimony, arsenic, the noble metals, mercury, selenium, silver, tin, and titanium require a modified sample digestion procedure and in all cases the method write-up should be consulted for specific instructions and/or cautions.

Note to Table IB Note 4: If the digestion procedure for direct aspiration AA included in one of the other approved references is different than the above, the EPA procedure must be used. Dissolved metals are defined as those constituents which will pass through a 0.45 micron membrane filter. Following filtration of the sample, the referenced procedure for total metals must be followed. Sample digestion of the filtrate for dissolved metals (or digestion of the original sample solution for total metals) may be omitted for AA (direct aspiration or graphite furnace) and ICP analyses, provided the sample solution to be analyzed meets the following criteria:

- a. has a low COD (<20),
- b. is visibly transparent with a turbidity measurement of 1 NTU or less,
- c. is colorless with no perceptible odor, and
- d. is of one liquid phase and free of particulate or suspended matter following acidification.

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³⁵ Precision and recovery statements for the atomic absorption direct aspiration and graphite furnace methods, and for the spectrophotometric SDDC method for arsenic are provided in Appendix D of this part titled, "Precision and Recovery Statements for Methods for Measuring Metals."

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⁴³ The application of clean techniques described in EPA's draft Method 1669: *Sampling Ambient Water for Trace Metals at EPA Water Quality Criteria Levels* (EPA-821-R-96-011) are recommended to preclude contamination at low-level, trace metal determinations.

3. Section 136.3 is amended by adding new paragraph (40) to read as follows:

§ 136.3 Identification of test procedures.

- (a) * * *
(b) * * *

* * * * *
(40) USEPA. 1999. Method 1631, Revision B, "Mercury in Water by Oxidation, Purge and Trap, and Cold Vapor Atomic Fluorescence Spectrometry." May 1999. Office of Water, U.S. Environmental Protection Agency (EPA 821-R-99-005). Available from: National Technical Information Service, 5285 Port Royal Road, Springfield, Virginia 22161. Publication No. PB99-131989. Cost: \$25.50. Table IB, Note 43.
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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 239

[FRL-6354-7]

Adequacy of State Permit Programs Under RCRA Subtitle D

AGENCY: Environmental Protection Agency.

ACTION: Direct final rule.

SUMMARY: The Environmental Protection Agency (EPA) is taking direct final action to streamline the approval process for specified States permit programs for solid waste disposal facilities other than municipal solid waste landfills (MSWLFs) that receive conditionally exempt small quantity generator (CESQG) hazardous waste. States whose subtitle D MSWLF permit programs or subtitle C hazardous waste management programs have been reviewed and approved or authorized by the Agency are eligible for this streamlined approval process if their State programs require the disposal of CESQG hazardous waste in suitable facilities. EPA is issuing an adequacy determination to the following State programs: Arizona, California, Colorado, Connecticut, Florida, Georgia, Illinois, Kentucky, Louisiana, Massachusetts, Michigan, Minnesota, New Hampshire, New York, North Carolina, North Dakota, Oklahoma, Ohio, Pennsylvania, Rhode Island, South Dakota, Tennessee, Utah, Vermont, Virginia, West Virginia, Wisconsin, and Wyoming.

Elsewhere in the proposed rule section of today's **Federal Register**, EPA is proposing the program adequacy of

these States and soliciting comment on this decision. If relevant adverse comments are received, EPA will withdraw this direct final rule of program adequacy and address the comments in a subsequent final rule document. EPA will not give additional opportunity for comment. If EPA receives relevant adverse comment concerning the adequacy of only certain State programs, the Agency's withdrawal of the direct final rule will only apply to those State programs. Comments on the inclusion or exclusion of one State permit program will not affect the timing of the decision on the other State permit programs.

DATES: This final rule will become effective September 7, 1999, unless EPA receives relevant adverse comment by July 8, 1999. Should the Agency receive such relevant adverse comments, EPA will withdraw this direct final rule and give timely notice in the **Federal Register**.

ADDRESSES: Commenters must send an original and two copies of their comments referencing docket number F-98-SAPP-FFFFF to: RCRA Docket Information Center, Office of Solid Waste (5305G), U.S. Environmental Protection Agency Headquarters (EPA, HQ), 401 M Street, SW, Washington, D.C. 20460. Hand deliveries of comments should be made to the Arlington, VA, address listed below. Comments may also be submitted electronically by sending electronic mail through the Internet to: rcradocket@epamail.epa.gov. Comments in electronic format should also be identified by the docket number F-98-SAPP-FFFFF. All electronic comments must be submitted as an ASCII file avoiding the use of special characters and any form of encryption.

Commenters should not submit electronically any confidential business information (CBI). An original and two copies of CBI must be submitted under separate cover to: RCRA CBI Document Control Officer, Office of Solid Waste (5305W), U.S. EPA, 401 M Street, SW, Washington, D.C. 20460.

Public comments are available for viewing in the RCRA Information Center (RIC), located at Crystal Gateway I, First Floor, 1235 Jefferson Davis Highway, Arlington, VA. The RIC is open from 9 a.m. to 4 p.m., Monday through Friday, excluding federal holidays. To review docket materials, it is recommended that the public make an appointment by calling 703-603-9230. The public may copy a maximum of 100 pages from any regulatory docket at no charge. Additional copies cost \$0.15/page. For information on accessing paper and/or

electronic copies of the document, see the **SUPPLEMENTARY INFORMATION** section.

Supporting materials for the final determination for Connecticut, Massachusetts, New Hampshire, Rhode Island, and Vermont are available for viewing by contacting Cynthia Greene, US EPA Region 1, 90 Canal Street, Boston, MA 02203, phone 617/565-3165.

Supporting materials for the final determination for New York are available for viewing by contacting John Filippelli, US EPA Region 2, 290 Broadway, New York, NY 10007-1866, phone 212/637-4125.

Supporting materials for the final determination for Pennsylvania, West Virginia, and Virginia are available for viewing by contacting Mike Giuranna, US EPA Region 3, 1650 Arch Street, Philadelphia, PA 19103-2029, phone 215/814-3298.

Supporting materials for the final determination for Florida, Georgia, Kentucky, North Carolina, and Tennessee are available for viewing by contacting Patricia Herbert, US EPA Region 4, Atlanta Federal Center, 61 Forsyth Street, Atlanta, GA 30303-3104, phone: 404/562-8449.

Supporting materials for the final determination for Illinois, Michigan, Minnesota, Ohio, and Wisconsin are available for viewing by contacting Mary Setnicar, US EPA Region 5, 77 West Jackson Blvd., Chicago, IL 60604-3590, phone 312/886-0976.

Supporting materials for the final determination for Louisiana and Oklahoma are available for viewing by contacting Willie Kelley, US EPA Region 6, 1445 Ross Avenue, Dallas, TX 75202-2733, phone: 214/665-6760.

Supporting materials for the final determination for Colorado, North Dakota, South Dakota, Utah, and Wyoming are available for viewing by contacting Gerald Allen, Region 8, US EPA 999 18th Street, Suite 500, Denver, CO 80202-2466, phone 303/312-7008.

Supporting materials for the final determination for Arizona and California are available for viewing by contacting Steve Wall, US EPA Region 9, 75 Hawthorne Street, San Francisco, CA 94105, phone 415/744-2123.

FOR FURTHER INFORMATION CONTACT: For general information, contact the RCRA Hotline at 800 424-9346 or TDD 800/553-7672 (hearing impaired). In the Washington, D.C., metropolitan area, call 703/412-9810 or TDD 703/412-3323.

For information on specific aspects of this direct final rule, contact Allen Geswein, Municipal and Industrial Solid Waste Division of the Office of