

40 CFR Part 81

[FRL-5279-7]

Designation of Areas for Air Quality Planning Purposes; Wyoming; Redesignation of Particulate Matter Attainment Areas**AGENCY:** Environmental Protection Agency (EPA).**ACTION:** Notice of proposed rulemaking.

SUMMARY: In this document, the EPA is proposing to approve the State of Wyoming's December 19, 1994 request to redesignate the Powder River Basin particulate matter attainment area to exclude the Kennecott/Puron Prevention of Significant Deterioration (PSD) Baseline area, pursuant to section 107 of the Clean Air Act. EPA is also proposing to designate the Kennecott/Puron PSD Baseline area as a separate particulate matter attainment area. In the final rules section elsewhere in this **Federal Register**, the EPA is acting on the State's request in a direct final rule without prior proposal because the Agency views this action as noncontroversial and anticipates no adverse comments. A detailed rationale for the action is set forth in the direct final rule. If no adverse comments are received in response to this proposed rule, no further activity is contemplated in relation to this rule. If the EPA receives adverse comments, then the direct final rule will be withdrawn and all public comments received will be addressed in a subsequent final rule based on this proposed rule. The EPA will not institute a second comment period on this document. Any parties interested in commenting on this document should do so at this time.

DATES: Comments on this proposed action must be received in writing by October 12, 1995.

ADDRESSES: Written comments should be addressed to Vicki Stamper, 8ART-AP, at the EPA Regional Office listed below. Copies of the documents relevant to this proposed rule are available for public inspection during normal business hours at the following locations: Air Programs Branch, Environmental Protection Agency, Region VIII, 999 18th Street, Suite 500, Denver, Colorado 80202-2466; and Air Quality Division, Wyoming Department of Environmental Quality, 122 West 25th Street, Hershler Building, Cheyenne, Wyoming 82002.

FOR FURTHER INFORMATION CONTACT: Vicki Stamper, 8ART-AP, Environmental Protection Agency, Region VIII, 999 18th Street, suite 500,

Denver, Colorado 80202-2466, (303) 293-1765.

SUPPLEMENTARY INFORMATION: See the information provided in the direct final rule of the same title which is located in the Rules Section of this **Federal Register**.

Dated: August 10, 1995.

Jack W. McGraw,
Acting Regional Administrator.

[FR Doc. 95-22151 Filed 9-11-95; 8:45 am]

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40 CFR Part 136

[FRL-5294-6]

A Public Meeting and Availability of Documents on Streamlining Approval of Analytical Methods at 40 CFR Part 136 and Flexibility in Existing Test Methods**AGENCY:** U.S. Environmental Protection Agency (EPA).**ACTION:** Notice of meeting and availability of documents.

SUMMARY: The Office of Science and Technology within EPA's Office of Water is conducting a public meeting on approaches to streamlining the proposal and promulgation of analytical methods at 40 CFR Part 136 under Section 304(h) of the Clean Water Act and increasing flexibility in existing 40 CFR Part 136 test methods. In this public meeting, EPA intends to discuss (1) procedures for streamlining the promulgation of new analytical methods under 40 CFR Part 136; (2) measures to provide increased flexibility for use of emerging technologies in analytical methods already promulgated at 40 CFR Part 136; (3) establishment of standardized quality control (QC) for analytical methods, including standardized procedures for development of QC acceptance criteria from single and interlaboratory data; (4) establishment of standardized data elements for reporting analytical results; (5) withdrawal of outdated methods; and (6) establishment of criteria by which the wastewater methods promulgated at 40 CFR Part 136 can be harmonized with other EPA program methods and with industry and association methods. The purpose of this notice is to provide information regarding the public meeting agenda, to make available documents concerning the Agency's streamlining effort, and to discuss the information and documents provided with this notice. This notice is not an advanced notice of proposed rulemaking, but is intended only to apprise persons of discussion topics at

upcoming public meetings. Nothing in this document is intended to have regulatory effect or to initiate any rulemaking process. Where the document discusses existing regulatory interpretations, such interpretations are guidance only and not themselves binding on EPA, State regulatory agencies, or the public to the extent they are inconsistent with the underlying regulations.

DATES: The public meeting on streamlining will be held Thursday, September 28, 1995, from 9:00 a.m. to 5:30 p.m.

ADDRESSES: The public meeting on streamlining will be held at the Federal Building in Seattle, Washington. See Supplementary Information for further details.

The documents made available with this notice can be obtained from Marion Thompson, Mail Code 4303, 401 M Street, S.W., Washington, DC 20460. Phone: (202) 260-7117. Facsimile: (202) 260-7185.

FOR FURTHER INFORMATION CONTACT: Questions concerning this notice can be directed to Marion Thompson by phone at (202) 260-7117 or by facsimile at (202) 260-7185.

SUPPLEMENTARY INFORMATION: Arrangements for the public meeting are being coordinated by DynCorp EENSP. For information on registration, contact Cindy Simbanin, 300 N. Lee Street, Suite 500, Alexandria, VA 22314. Phone: (703) 519-1386. Facsimile: (703) 684-0610. Space is limited and reservations are being taken on a first come, first served basis. No fees will be charged to attend. Hotel reservations may be made by contacting the Crowne Plaza Hotel in Seattle at (800) 521-2762. Guest rates are \$83 single and \$106 double occupancy, including tax. Reservations must be made by 9/8/95, and you must specify that you are attending the EPA Workshop to qualify for the group rate. Accommodations are limited, so please make your reservations early.

I. Background

Section 304(h) of the Clean Water Act (CWA) requires the EPA Administrator to promulgate guidelines establishing test procedures for data gathering and monitoring under the Act. These test procedures (analytical methods) are promulgated at 40 CFR Part 136. EPA uses these analytical methods to support development of effluent guidelines promulgated at 40 CFR Parts 400-499. These procedures we also used to establish compliance with National Pollutant Discharge Elimination System

(NPDES) permits and for other purposes.

A. 40 CFR Part 136 Methods

Until April of 1995, proposal and promulgation of analytical methods for wastewater at 40 CFR Part 136 had been the responsibility of EPA's Office of Research and Development (ORD), specifically, the Environmental Monitoring Systems Laboratory in Cincinnati, Ohio (EMSL-Ci). In April of 1995, EPA restructured its research laboratories and transferred responsibility for proposal and promulgation of analytical methods for wastewater to the Engineering and Analysis Division (EAD) within the Office of Water's (OW's) Office of Science and Technology (OST).

One objective in implementing transfer of the 304(h) program was to better serve the needs of the regulated community, State and Regional permitting authorities, and environmental laboratories, by centralizing the methods overall responsibility for effluent guidelines methods and associated compliance monitoring methods into a single office. This centralization of responsibility should allow EPA to better respond to the needs of these communities by expediting the current method modification and approval process. Specific goals for streamlining the program are to:

(1) Decrease the time and Agency resources required to approve new analytical techniques and improved methods,

(2) Provide for an increase in the number of methods that are approved for use each year,

(3) Increase participation of outside organizations in the method development process, and

(4) Improve overall program quality.

In order to achieve these goals, EPA is considering development of a 304(h) program framework that is based on the following key elements:

- Increased flexibility to modify approved methods,
- Standardized QA/QC protocols to be required for all new methods,
- Standardized procedures for generating QC acceptance criteria,
- Standardized procedures for validating methods at minimal expense,
- A standardized method format,
- Standardized procedures for submitting methods to EPA for approval,
- Standardized processes for reviewing and approving methods, and
- Increased stakeholder involvement in 304(h) program implementation.

B. Public Meetings

EPA plans to conduct at least three public meetings, the public meeting announced in this notice and two others to be announced separately, to solicit input and recommendations concerning the 304(h) streamlining initiative. In addition, EPA is soliciting support and expertise from each of the groups that have developed methods already approved for use under the 304(h) program. These groups include the AOAC-International (formerly the Association of Official Analytical Chemists), the American Society for Testing and Materials (ASTM), the American Public Health Association (APHA), the Water Environment Federation (WEF), the U.S. Geological Survey (USGS), and the American Water Works Association (AWWA). Many of these groups can offer valuable insight concerning problems with the current program and recommended areas of improvement. Also, some of these groups have developed or are developing standardized procedures for the areas listed above. In these instances, EPA plans to build upon the experience and efforts of those organizations. For example, the method validation procedures described later in this notice are based on the standardized method validation protocols developed by AOAC-International and ASTM and are adapted as necessary to meet EPA's regulatory objectives.

C. Increased Flexibility in the 304(h) Program

In developing its preliminary plans for improvement of the 304(h) program, EPA concluded that the success of the program would depend on its ability to reflect the latest advances in analytical technology. This, in turn, would require that the program be efficient and flexible enough to encourage the development of new methods and technology by organizations outside of EPA. Specifically, the program must provide:

- A well-defined QC/QA program that is stringent enough to meet compliance monitoring objectives associated with the program but flexible enough to be applied to a wide variety of analytical procedures,
- A well-defined system of classifying new techniques as either new methods or as modifications to existing methods,
- A flexible framework in which already approved methods can be modified, and
- The flexibility to modify processes for submitting new methods based on lessons learned.

Advantages of increased program flexibility are expected to be shared widely by EPA, by purveyors of new technology, and by permittees, permit writers, and analytical laboratories. In addition, this inherent method flexibility, along with a well-defined program for developing and approving new methods, will provide research laboratories, instrument vendors, and equipment manufacturers with incentives for developing new analytical techniques. This, in turn, will provide permittees and permit writers with greater flexibility in selecting analytical methods that yield improved performance in specific discharge situations.

Finally, a more flexible program is consistent with this Administration's Environmental Technology Initiative. The initiative, which was announced by President Clinton in February 1993, is intended to accelerate environmental technological innovation as a means of strengthening America's economy and creating jobs while enhancing environmental protection. EPA believes that the incentives provided by a more flexible program will spur the development of new technologies, and with it new jobs. In addition, EPA anticipates that the use of new technologies may lower the cost of environmental measurements, thereby reducing costs of environmental compliance for industries and municipalities.

In seeking increased program flexibility, EPA has sought to develop a strategy that balances the advantages described above against concerns that results produced with new technologies may not be equivalent to results produced by the approved 40 CFR Part 136 methods. The core of this strategy is a well-defined QA/QC program that can apply to all approved methods and method modifications.

The remainder of this notice outlines a framework in which the key elements listed above can be implemented to meet EPA's streamlining objectives. This framework will be discussed at the public meetings on streamlining. Section II describes OST's vision for increased flexibility within the 304(h) program itself and for increased flexibility within specific methods approved under the program. Section II also describes the standardized QC framework on which this program and method flexibility is based and outlines requirements necessary to document equivalency of alternate techniques used in the program. Section III describes procedures that can be used to develop acceptance criteria for the standardized QC tests outlined in

Section II. Section IV describes standardized procedures for submitting new methods, including a standardized format for documenting new methods, standardized procedures for validating new methods, and standardized procedures for submitting validated methods to EPA for approval.

II. Method Flexibility

On October 26, 1984, EPA addressed the flexibility allowed in the wastewater methods with the promulgation of a major set of methods at 40 CFR Part 136 Appendix A for determination of organic analytes (49 FR 43234). In that promulgation, EPA stated that flexibility would be allowed in certain parts of the analytical methods, provided that equivalency could be demonstrated. This notice describes a methods system in which greater flexibility is allowed.

A. Interpretations of Flexibility

EPA has received several requests for interpretation of the flexibility allowed by the 40 CFR Part 136 methods, and EPA's Office of Research and Development (ORD) and Office of Science and Technology (OST) have provided technical interpretations of these requests. Interpretations made to date are provided in a document titled Technical Interpretation of Method Flexibility that is made available with this notice. These interpretations further clarify the flexibility of the 40 CFR Part 136 methods given in the 1984 final rule (49 FR 43234).

B. Alternate Methods

The current means by which organizations may seek approval of alternate methods is described at 40 CFR Sections 136.4 and 136.5. If an alternate method is to be applied to a specific discharge, section 136.4 requires the person submitting the request to file a limited approval application with the Administrator of the EPA Region in which the discharge occurs. If permission is sought to use the alternate method for nationwide use, a nationwide approval application must be filed with the Director of EMSL-Ci. In most instances, Regional Administrators have deferred decisions concerning limited approval to the Director of EMSL-Ci. To support its approval process, EMSL-Ci developed extensive requirements for the data needed to demonstrate that an alternate method produces results that are equal to or better than results produced by the approved method. This alternate test procedure (ATP) process has worked well for persons willing to invest the resources required. EPA seeks a public discussion of whether the ATP process

should be continued, particularly in the context of the adoption of the streamlining process contemplated by this notice.

In contrast to continuing the ATP process, EPA has received numerous comments at its technical symposia and in other venues that the ATP process is cumbersome, and that the data gathering required is much more extensive than is necessary to demonstrate that a simple method modification does not materially affect the results produced by that method. Against this view, many permitting agencies interpret the words in an analytical method very literally and allow no changes whatsoever. In many cases, narrow interpretation may be justified, in that the permitting authority may have experienced situations in which certain unscrupulous dischargers or laboratories have taken shortcuts that ultimately compromised the analytical results produced. If this compromise results in compliance with a permit limit when use of the approved, unmodified method would result in noncompliance, a narrow, restrictive interpretation would be justified.

EPA now intends to describe the conditions under which minor method modifications would be allowed and would be considered within the scope of a method. One approach to this issue is described below and will be discussed during the public meetings announced in this notice. There may be other approaches. Therefore, EPA seeks input from the public, particularly from the regulating and regulated communities, as to the workable set of conditions under which method modifications should be allowed.

C. Front-End Method Modifications

For purposes of the public meetings, EPA plans to consider changes to all but the determinative step in an analytical method as being within the scope of that method. The determinative step is the physical/chemical process by which the actual measurement is made. For most methods, the determinative step is an instrumental determination. Titration, colorimetry, inductively coupled plasma atomic emission spectroscopy (ICP/AES), high resolution gas chromatography combined with high resolution mass spectrometry (HRGC/HRMS), and reading a color change in an immunoassay are all examples of the determinative step.

All "front-end" devices and processes employed prior to the determinative step, including sampling, sample extraction/digestion, sample cleanup, and sample introduction, are not considered to be part of the

determinative step. In addition, changes to data processing and other techniques that occur after the determinative technique rarely impact data reliability.

One objective of providing flexibility to modify approved methods is intended to allow laboratories a means by which to reduce the generation of laboratory wastes without having to undergo elaborate comparison studies and a time-consuming approval process. The front-end flexibility described in this notice is based on an in-house laboratory comparison of QC sample results generated using the modified method. Once the laboratory has successfully demonstrated that the modified method is comparable to the approved 40 CFR Part 136 method (Reference Method), the laboratory would be able to implement the changes immediately. Section II.E. of this notice outlines procedures that may be required to demonstrate method comparability.

1. Examples of Determinative Techniques

As described above, a method that uses a different determinative technique would be either a modification of another, existing, EPA-approved method or is a new method. The factors to be considered in establishing that the determinative technique is the same as that in an existing method are (1) the physical/chemical nature of the measurement process and (2) the specificity of the measurement for the analyte(s) of interest. If either or both of these factors are different from an existing method for the analyte(s) of interest, the determinative step is not the same and the procedure would not be considered to be a new method.

For example, the use of a horizontal torch in an ICP is not a different determinative technique because neither the physical/chemical process nor the specificity of the measurement is changed. Similarly, the use of a magnetic sector in place of a quadrupole in a low resolution mass spectrometer (LRMS) is not a change in the determinative technique because neither the physical/chemical process nor the specificity of measurement is changed. On the other hand, the addition of a mass spectrometer to the ICP results would be a change in both the physical/chemical process and the specificity, and use of a high resolution mass spectrometer in place of the LRMS results in a change in specificity, even though the physical/chemical nature of the process is not changed.

Further, and as one of EPA's internal reviewers has pointed out, the determinative technique may be the

least variable part of the entire analytical process. Therefore, although this notice provides one approach to flexibility in which the determinative process would be fixed, EPA seeks to discuss how this flexibility could be quantified and controlled to allow use of alternate determinative techniques without compromising the specificity of a method for the analyte(s) of interest and without making the flexibility so broad that the method protocol becomes meaningless.

2. List of Candidate Front-End Techniques

This use of the physical/chemical nature and specificity of the determinative technique to describe fundamental method changes would result in the conclusion that all analytical processes that occur prior to the determinative technique and that do not adversely affect method performance could be considered within the scope of a method. To facilitate an understanding of such front-end techniques that could be considered within the scope of existing 40 CFR Part 136 methods, EPA has compiled a list titled Front-end Techniques that are Candidates for Method Modification Under EPA's Method Flexibility Overture. This list, which is based on a review of methods promulgated at 40 CFR Part 136 and on discussions of some of these techniques at technical symposia and with instrument vendors and other suppliers of analytical equipment, is made available with this notice. EPA emphasizes that this would not be a list of approved techniques, nor would this list be all-inclusive. The list is merely intended to provide examples of the types of procedural modifications that may fall within the flexibility of approved methods. Presently, substitution of these techniques in a method approved for use under 40 CFR Part 136 is allowed only when these techniques are listed in the approved method or under the conditions described in the document titled Technical Interpretation of Method Flexibility that is also made available with this notice.

3. Cautions That All Techniques May Not Produce Equivalent Results

EPA wishes to emphasize that not all techniques may produce results equivalent to the techniques employed in the 40 CFR Part 136 methods. This is particularly true for "method-defined" analytes. A method-defined analyte is one in which the analytical result obtained depends totally on how the measurement is made. Therefore, changes to specific analytical protocols

have the potential of changing the numerical value of the results for a given sample. For example, the conventional pollutant "oil and grease" (40 CFR 401.16) is defined by the exact procedure used. In attempting to find a solvent to replace Freon-113 for the determination of oil and grease, EPA has found that no solvent produces results exactly equivalent to the results produced by Freon-113 on the range of environmental samples tested. Extreme care must therefore be exercised in making changes to the analytical techniques used in the determination of these method-defined analytes.

Even for analytes that are not method-defined, differing analytical techniques can produce varying results. Examples of techniques that have come to EPA's attention are differences produced by separatory funnel and continuous liquid-liquid extractors in the extraction of phenolic compounds by EPA Method 625 and with other methods in which phenolic compounds are determined. Similarly, EPA has observed differences produced by separatory funnel and stir-bar extraction techniques for certain pulp mill wastewaters using Method 1653 and differences produced by batch versus column adsorption techniques for certain pulp mill wastewaters using Method 1650.

One possible solution to this problem would be to require that each modified method be used to analyze a matrix spike/matrix spike duplicate pair on each dissimilar matrix. Another possible solution is to require testing of each modified method on each and every specific discharge to which the modified method is to be applied. EPA employed this philosophy in the development of Method 1664 for the determination of oil and grease. Method 1664 would require demonstration of equivalency using analytical standards spiked into reagent water and testing of the specific discharge unless the concentration of oil and grease in the discharge is not detectable.

Finally, it has been suggested that it is necessary to define methods by the extraction/digestion procedure and the determinative step in order to ensure that results produced through a modified method are truly comparable. For example, it has been suggested that without this stricter definition of methods, total metals digestions could be omitted and still yield acceptable recoveries of metals from spiked samples. One possible solution to this problem would be to modify the QC requirements to require spiking of various forms of target analytes, as appropriate to the method. For example, laboratories testing for total metals

would be required to include organic, inorganic, highly soluble, and relatively insoluble species of the metals of interest in their spike solutions when demonstrating method equivalency. Another possible solution would be to simply limit the flexibility outlined above and in the document entitled Front-end Techniques that are Candidates for Method Modification Under EPA's Method Flexibility Overture by omitting all techniques associated with sample extraction or digestion.

D. Standardized Quality Control

In order to establish that a front-end change will not degrade method performance, a reference against which the change is made would be needed. For the purposes of the public meetings, the reference would be the method promulgated at 40 CFR Part 136. The definitive test criteria against which performance of the front-end modification would be assessed would be the QC acceptance criteria in the promulgated method. For those methods that do not contain QC acceptance criteria, these criteria would be developed using performance data in the promulgated 40 CFR Part 136 method. See the discussion in Section III of this notice on how EPA would establish these criteria.

The QC acceptance criteria would be based on the standardized quality control (QC) described below. This standardized QC includes QC tests that can be used to demonstrate that a front-end change would not adversely affect method performance. EPA would like to apply this standardized QC to all methods to be proposed at 40 CFR Part 136 in the future. EPA would also like to apply this standardized QC to all applicable methods and analytes that are already approved for use at 40 CFR Part 136. Applicability includes all chemical analytical methods, and, with some modification, many of the radiological methods and physical methods. EPA is in the process of developing corresponding QC requirements for determining the equivalence of toxicity testing procedures and may include this corresponding QC in a subsequent notice or proposal.

1. Standardized QC in the 40 CFR Part 136 Methods

The standardized QC program envisioned by EPA would be based on the QC program detailed in Section 8 of each method published at 40 CFR 136, Appendix A. For the purpose of providing a solid foundation on which to build the method and program

flexibility described in this notice, EPA has updated and expanded the standardized QC that is detailed in these methods to ensure reliable measurements. The expanded and updated standardized QC that EPA plans to use would be as follows:

- Initial calibration—a minimum of five concentrations of analytical standards for the analyte(s) of interest, one near the method detection limit (MDL; 40 CFR 136, Appendix B), and one near the upper end of the calibration range. The nature of the calibration function allowable is specified in the method or, in the absence of such specifications, can be developed from performance data using the procedures outlined in Section III of this notice. Examples of the calibration function include: linear through the origin, linear not through the origin, or quadratic through or not through the origin. Calibration functions higher than second order (quadratic) would not be allowed. Limits on the calibration function are also specified in the method or, in the absence of such specifications, can be developed from performance data. For example, if linearity through the origin is used, some limit on the linear fit should be stated. In the Appendix A methods, this limit is specified as the percent relative standard deviation of the response factor or calibration factor. Laboratories seeking to exercise the front-end method flexibility described in this notice would be required to meet all initial calibration acceptance criteria when using the modified technique.

- Calibration verification—periodic verification that instrument performance has not changed significantly. This verification is based on time (e.g., a working day or 12-hour shift) or on the number of samples analyzed (e.g., after every 10th sample). QC acceptance criteria are given in the approved method or can be developed for each analyte using the procedures outlined in Section III of this notice. Laboratories seeking to exercise the front-end method flexibility described in this notice would be required to meet these QC acceptance criteria when using alternate front-end techniques. Most methods approved under this program specify corrective action that the analyst is to take when calibration is not verified, e.g., that all samples analyzed since the last verified calibration must be reanalyzed, or that the surrogate and matrix spike recoveries should be used to determine if results for a given sample are valid. Under the standardized QC program envisioned by EPA, this required action would be extended to all methods already

approved for use at 40 CFR Part 136 and to all new methods submitted for approval.

- Initial demonstration of laboratory capability—analysis of four reagent water samples spiked with the analyte(s) of interest and carried through the entire analytical process. This test is performed by the laboratory before it utilizes the method for analysis of actual field samples. In the 1600 series methods, this test is termed the “initial precision and recovery” (IPR) test. In other venues, it has been termed the “start-up” test. All four reagent water samples used in the test are spiked with the same solution, but the concentration of target analytes in the spike solution may vary between one and five times the lowest concentration used to establish the initial calibration curve. Laboratory performance is assessed in terms of the average percent recovery and the standard deviation of recovery. QC acceptance criteria for each analyte and consequences of failing the IPR test are given in the 40 CFR 136, Appendix A methods. For other methods, the procedures outlined in Section III of this notice can be used to develop QC acceptance criteria. Under the standardized QC program envisioned by EPA, corrective action required for failing to meet these criteria would be to correct the problem and repeat the test prior to the analysis of field samples. Laboratories seeking to exercise the front-end flexibility described in this notice would be required to produce acceptable IPR test results using the modified method technique.

- Analysis of blanks—either periodically or with each sample batch. The period or batch size is defined in each method. QC acceptance criteria are given in each method or can be developed for the concentration or amount of analyte allowed in the blank. Under the standardized QC program envisioned by EPA, the consequence of failing to meet the acceptance criteria will be to identify and eliminate the source of contamination and reanalyze the sample batch with which the blank is associated. Laboratories seeking to exercise the front-end method flexibility outlined in this notice must be capable of producing acceptable blanks when using the alternate techniques.

- Analysis of a matrix spike (MS) and matrix spike duplicate (MSD)—the analytes of interest are spiked into splits of an actual field sample, and the recovery of the analytes is used to assess method performance on that sample matrix. (For isotope dilution analyses, the MS/MSD analyses are not required because every sample is spiked.) QC

acceptance criteria for spike recovery and for the relative percent difference (RPD) in results between the MS/MSD pair are given in the methods. In the absence of such specifications, recovery and RPD acceptance criteria can be developed from performance data using the procedures outlined in Section III of this notice. Unless otherwise stated in the approved method, EPA envisions that the normal consequence of failing the MS/MSD test will be to reanalyze the sample batch with which the MS/MSD are associated. Laboratories seeking to exercise the front-end flexibility described in this notice would be required to analyze an MS/MSD pair on each new matrix. If results of these MS/MSD analyses fail to meet the acceptance criteria, the laboratory would be required to conduct more extensive studies of the modified method on that matrix.

- Ongoing demonstration of laboratory capability—analysis of a single reagent water sample spiked with the analyte(s) of interest. This sample is carried through the entire analytical process to demonstrate that the laboratory is in control and to allow separation of laboratory performance from method performance on the sample matrix. In the 40 CFR 136, Appendix A methods, this sample is referred to as a “quality control check sample.” In other venues, this analysis has been termed the “ongoing precision and recovery” (OPR) analysis, the “laboratory control sample” (LCS), and the “laboratory-fortified blank” (LFB). QC acceptance criteria for each analyte in this sample are given the approved method, or in the absence of such criteria, can be developed from performance data using the procedures described in Section III of this document. Unless otherwise stated in the approved method, EPA envisions that the consequence of failing the OPR test will be to reanalyze the sample batch with which the OPR is associated.

- Method detection limit (MDL)—nearly all of the 40 CFR 136, Appendix A methods contain MDLs, although few of the methods explicitly require laboratories to demonstrate their ability to achieve these MDLs. Methods recently published by OST and by ORD, however, have required laboratories to demonstrate their ability to achieve specified MDL objectives. Under the standardized QC program envisioned by EPA, MDLs would be used as an indicator of method performance. MDLs, or the embodiment of some other detection limit concept, should be developed for each analyte in each method, and each laboratory that intends to practice a method should be

required to demonstrate that the MDL(s) or equivalent detection limit concept can be achieved prior to practice of the method. As envisioned by EPA in the system contemplated by this notice, this requirement would apply to the analytes of interest only.

- Analysis of a reference sample from a source external to the laboratory—the most common reference sample is a Standard Reference Material from the National Institute of Standards and Technology (NIST). The reference sample and the period for its use are specified in each method. EPA is considering setting acceptance criteria for standard reference materials to be within some percentage of the true value based on the variability of measurement for that analyte. One possible indicator of that variability is the relative standard deviation calculation for the initial precision and recovery samples. Corrective action to be taken when the acceptance criteria are not met should involve identifying the samples affected, determining the amount of the effect, and if the effect is significant, determining the impact of the effect on the environmental samples analyzed and advising the affected parties.

2. Standardized QC in Other Method-Developing Organizations

During the last several years, EPA has worked closely with ASTM toward the development of standardized QC for incorporation into ASTM methods. One product of this effort is a draft document entitled Standard Practice for Writing Quality Control Specifications for Test Methods for Organic Constituents, which has been approved by the ASTM Committee D-19 on Water. This document, which is made available with this notice, requires standardized QC in all future editions of organic methods and describes how criteria are to be calculated from the results of an interlaboratory method validation study. The main difference between the QC requirements outlined in this document and those produced today is the lack of an ASTM requirement to determine MDLs.

EPA has also worked closely with the Environmental Quality Committee of AOAC-International to standardize and collaboratively test methods that contain comparable QC requirements and performance-based QC criteria. More recently, EPA has begun working with the American Public Health Association, American Water Works Association, and Water Environment Federation toward standardization of QC to be used for methods published in Standard Methods for the Examination

of Water and Wastewater and promulgated at 40 CFR Part 136. Similarly, EPA has begun working more closely the U.S. Geological Survey (USGS) toward standardization of QC for USGS methods promulgated at 40 CFR Part 136.

EPA plans to continue efforts with these organizations to advance the universal adoption of standardized QC that would facilitate rapid proposal of methods produced by these organizations at 40 CFR Part 136. Further, if the methods developed by these organizations meet or exceed the needs of the Agency, EPA would rely on these organizations as primary method developers and could focus its own efforts on specialized methods or on esoteric methods needed to support regulation development or compliance monitoring.

E. Requirements for Documenting Front-End Method Equivalency

Under the program envisioned by EPA, flexibility in existing methods will apply to any change in one or more front-end devices and processes as long as these changes do not adversely affect method performance. In exercising this flexibility, laboratories will be required to demonstrate and document that the changes implemented will produce results that are comparable to or better than those produced by the Reference Method.

Demonstration that the method will meet or exceed the performance of the Reference Method and/or regulatory goals requires laboratories to perform the applicable QC tests outlined in Section II.D.1 of this notice and meet the applicable QC acceptance criteria associated with each test. Laboratories that exercise the flexibility offered by this program will be required to maintain all equivalency documentation on file and submit it to their clients (data users) upon request. Permittees that exercise the flexibility offered by this program will be responsible for ensuring that equivalency has been demonstrated by their in-house or contract laboratories and for ensuring that documentation can be provided to permitting authorities upon request.

At a minimum, documentation of method equivalency will include all raw results and summary data generated for each of the QC elements required. Alternatively, laboratories, permittees, or permitting authorities may elect to utilize the checklist provided and described in a document titled Methods Considered Within the Scope of Existing Wastewater Methods Under the EMMC Performance-based Methods System

(EMMC PBMS Guidance), made available with this notice.

Minimum data elements that EPA believes must be retained on file (and made available on request) to demonstrate equivalency are as follows.

1. The organization and method number for the modified 40 CFR Part 136 method (Reference Method) used for the measurement.

2. A detailed narrative discussing the modification(s) to the Reference Method. This narrative should provide (1) a detailed description of the changes made to the Reference Method, (2) the reasons for the change, (3) the supporting logic behind the technical approach to the change, and (4) the result of the change. The narrative should be written by an analytical chemist and written in terms that another analytical chemist can understand.

3. A summary level report or data reporting forms listing the pollutants, along with their CAS Registry numbers, for which the modifications were made.

4. A summary of all quality control results required by the Reference Method. These results include, but are not limited to, the following:

- Method-specific instrument tuning.
- Calibration.
- Calibration verification.
- Initial precision and recovery.
- Ongoing precision and recovery.
- Matrix spike and matrix spike duplicate results.
- Surrogate recoveries.
- Internal standard recoveries.
- Labeled compound recoveries.
- Method of standard additions.
- Spectral interference checks.
- Serial dilutions.
- Blank results.
- Quality control charts and limits.
- MDL study results.

Specific QC results vary according to the Reference Method and the instrument used in the determinative step. For example, labeled compound recoveries are associated only with methods that are based on isotope-dilution techniques, and spectral interference checks are typically associated with ICP-AES analyses.

5. Raw data that will allow an independent reviewer to verify each determination and calculation performed by the laboratory.

This verification should consist of tracing the instrument output (peak height, area, emission intensity, or other signal intensity) to the final result reported. Raw data are method and instrument specific and may include, but are not limited to the following:

- Sample numbers or other identifiers used by the both the permittee and the laboratory.

- Sample preparation (extraction/digestion) dates.
- Analysis dates and times.
- Sequence of analyses or run logs.
- Sample weight or volume.
- Extract volume prior to each cleanup step.
- Extract volume after each cleanup step.
- Final extract volume prior to injection.
- Digestion volume.
- Titration volume.
- Percent solids or percent moisture.
- Matrix modifiers.
- Dilution data, differentiating between dilution of a sample and dilution of an extract or digestate.
 - Instrument (make, model, revision, modifications) and operating conditions.
 - Sample introduction system (ultrasonic nebulizer, hydride generator, flow injection system, etc.).
 - Column conditions (manufacturer, length and diameter, stationary phase, solid support, film thickness, chelating or ion exchange resin, etc.).
 - Analysis conditions (char/ashing temperatures, temperature programs, incident rf power, flow rates, plasma viewing height, etc.).
 - Detectors (type, wavelength, slit, analytical mass monitored, etc.).
 - Chromatograms, ion current profiles, bar graph spectra, library search results.
 - Background correction scheme.
 - Quantitation reports, data system outputs, and other data to link the raw data to the results reported. (Where these data are edited manually, explanations of why manual intervention was necessary must be included).
 - Direct instrument readouts; i.e., strip charts, mass spectra, printer tapes, etc., and other data to support the final results.
 - Laboratory bench sheets and copies of all pertinent logbook pages for all sample preparation and cleanup steps, and for all other parts of the determination.

The raw data required should be provided for all calibrations, verifications, blanks, matrix spikes and duplicates, and other QC analyses required by the Reference Method as well as any field samples analyzed by the method. Data should be organized so that an analytical chemist can clearly understand how the analyses were performed.

6. Example calculations that will allow the data reviewer to determine how the laboratory used the raw data to arrive at the final results.

Useful examples include both detected compounds and undetected

compounds. If the laboratory or the method employs a standardized reporting level for undetected compounds, this should be made clear in the example, as should adjustments for sample volume, dry weight (solids only), etc.

7. For GC/MS and other instruments involving data systems, the permittee should be prepared to submit raw data on magnetic tape or disk, upon request by the regulatory authority.

8. The names, titles, addresses, and telephone numbers of the analysts who performed the analyses and of the quality control officer who will verify the analyses.

If data are collected by a contract laboratory, the permittee will be responsible for ensuring that all of the requirements in the methods are met by the contract laboratory and that all data listed above are provided.

III. Development of QC Acceptance Criteria

Few of methods promulgated at 40 CFR Part 136 contain QC acceptance criteria for all of the standardized QC elements outlined in this notice. (The notable exceptions are the methods published at 40 CFR 136, Appendix A.) As described above, however, QC acceptance criteria are the principle means by which a front-end method modification can be judged to provide results equivalent to or better than results produced by the Reference Method. For those methods that do not contain QC acceptance criteria, EPA plans to employ one of three sources of data for developing these criteria. These sources are (1) interlaboratory study data contained in the promulgated 40 CFR Part 136 analytical method, if available, (2) water supply (WS) and water pollution (WP) study data, or (3) single-laboratory data contained in the promulgated analytical method. In explanation, WS and WP study data result from laboratory performance evaluations conducted periodically by EPA's National Environmental Research Laboratory at Cincinnati (NERL-Ci, formerly EMSL-Ci). By following the statistical techniques described below and detailed in the accompanying supporting document, these WS and WP data, or the performance data contained in an existing analytical method promulgated at 40 CFR Part 136, can be used to establish QC acceptance criteria.

As of the date of publishing this notice, EPA has not developed a means for developing QC acceptance criteria for a method for which EPA has neither WS/WP study data nor performance data, and until such means are developed, EPA will not allow

modification of promulgated 40 CFR Part 136 methods for which these data are not available. Although EPA has not surveyed all methods promulgated at 40 CFR Part 136, the Agency believes that the number of methods that (1) do not contain QC acceptance criteria, (2) are not covered by the WS/WP studies, or (3) do not contain performance data, is small. EPA seeks a public discussion of how to establish QC acceptance criteria when data on which to base these criteria are not available.

A. Development of QC Acceptance Criteria From Interlaboratory Study Data

ASTM and AOAC-International have published extensive literature on the statistical treatment of data for interlaboratory collaborative testing of analytical methods, including "ASTM D-2777" and Guidelines for Collaborative Study Procedure to Validate Characteristics of a Method of Analysis, JAOAC 72 No. 4, 1989. EPA's Office of Research and Development (ORD) and Office of Science and Technology (OST) have used the ASTM and AOAC-International statistical procedures to produce QC acceptance criteria for analytical methods published by their offices. The specific embodiment of the procedures as used by OST are given in an OST document titled Development of QC Acceptance Criteria, made available with this notice. EPA plans to work with AOAC-International and ASTM to conform these procedures as much as is practicable.

B. Development of QC Acceptance Criteria From WS/WP Study Data

EPA is considering use of WS/WP study data to establish QC acceptance criteria for an analytical method for which these criteria have not been developed. The procedures used will be the same or similar to those in ASTM D-2777 and detailed in the Development of QC Acceptance Criteria document referenced above. EPA envisions that this development will be conducted internally by EPA on an as-needed basis for methods, and that the acceptance criteria will then be proposed for promulgation at 40 CFR Part 136.

C. Development of QC Acceptance Criteria From Method Performance Data

Although few of the methods promulgated at 40 CFR Part 136 have QC acceptance criteria, most of these methods do contain performance data. Usually, these data reflect method performance in a single laboratory. Using the procedure given in the

document titled Development of QC Acceptance Criteria, these performance data can be used to establish QC performance criteria. Basically, this procedure uses the recovery and standard deviation of recovery to establish the QC acceptance criteria, with an additional allowance for interlaboratory variability where applicable. Exact details of these procedures are given in the Development of QC Acceptance Criteria document that is made available with this notice.

IV. Submission of New Methods

The process EPA envisions for submission of new methods encompasses the elements described in this notice. These elements are as follows:

- The method would be written using the guidelines and format described in Section IV.A.,
- The method would incorporate the standardized QC elements described in Section II.E.,
- QC acceptance criteria would be included in the method as described in Section III, and
- The method would be validated for single-use, single-industry use, or nationwide use, as described in Section IV.B.

A. Standardized Method Format

Made available with this notice is a document titled Guidelines and Format for Methods to be Proposed at 40 CFR Part 136. This document is a further development of the Guidelines and Format for EMSL-Cincinnati Methods (EPA-600/8-83-020) produced by EMSL-Ci in 1983. In turn, the Guidelines and Format for EMSL-Ci Methods was based on the ASTM's Form and Style for ASTM Standards, 5th ed., June 1980 (13-000001-80). The Guidelines and Format for Methods to be Proposed at 40 CFR Part 136 incorporates several important aspects of the information presented in this notice. It also incorporates the analytical methods format prescribed by EPA's Environmental Monitoring Management Council (EMMC). The EMMC format is directed at standardizing all Agency analytical methods.

For new methods submitted under the program discussed in this notice, a guideline and format from another organization may be used provided it is standardized and contains the same elements specified in this document. For example, the method format documents from the APHA, AWWA, and WEF for Standard Methods for Examination of Water and Wastewater, and from ASTM, AOAC-International,

and USGS are acceptable because these formats are documented and routinely followed by these organizations. Methods produced or approved by organizations that allow random formats would be required to be revised into a standardized format before submission for proposal at 40 CFR Part 136. This requirement would preclude confusion in methods.

B. Method Validation

For purposes of the streamlining contemplated by this notice, EPA presents a tiered approach to validation of new methods. This approach consists of three tiers, dependent on the intended application of the new method. The tiers are single use, use within a given industry, and nationwide use, and the levels of validation required for new or alternate methods are consistent with these uses. As discussed above, only those methods that contain a new or alternate determinative technique would be required to undergo method validation studies.

1. Tier I—Validation of Single-Use Methods

A single-use method would be applicable to a single discharge. Validation would be on that discharge and the method would be applicable to that discharge only. EPA believes that this tier would codify the present flexibility understood to be permitted in monitoring by encouraging permitting authorities and individual dischargers to determine unusual analytes of regulatory concern and to overcome matrix interferences. Method validation would consist of running four replicate tests in a single laboratory to establish single-laboratory performance data and applying the procedures given in the document titled Development of QC Acceptance Criteria to establish QC acceptance criteria for the method from the single-laboratory data.

2. Tier II—Validation of Single-Industry Methods

This tier would be applicable to discharges in a given industry by industrial category or subcategory. Categorical effluent guidelines limitations are promulgated at 40 CFR Parts 400-505. Method validation would consist of running tests of a minimum of one sample from a waste stream from three different facilities in three separate laboratories (a total of nine analyses) to establish laboratory performance data for the QC tests specified in this notice. These performance data would then be used to establish QC acceptance criteria using

the document titled Development of QC Acceptance Criteria.

3. Tier III—Validation of Methods for Nationwide Use

Nationwide-use methods would be validated in one of two ways: (1) A classical interlaboratory study would be performed using study designs such as those used by EPA in past studies or by AOAC-International or ASTM and QC acceptance criteria would be developed using the traditional variance components analysis, or (2) a study design that attempts to include all variance components could be used. For example, QC acceptance criteria could be developed by running tests in waste streams from a minimum of nine industrial categories in nine separate laboratories (a total of nine analyses). One of the nine waste streams would be required to be from a publicly owned treatment works (POTW) to ensure coverage of this industrial category. Although the individual variance components would not be known, the overall variance could be estimated from the study. The advantage of this second approach is that the number of tests, and therefore the cost, is minimized. Further details of the use of these two approaches is given in the Development of QC Acceptance Criteria document made available with this notice. EPA seeks a public discussion of the utility of these two approaches.

In order to implement this tiered approach, it is likely that a new table or tables would be published in 40 CFR Part 136 to define the level of validation and use for a method as well as the specific discharge and industrial category for methods that would be proposed and promulgated at Tiers I and II.

As with the other aspects of this notice, EPA seeks a public discussion of this tiered approach and suggestions for other approaches that may be more efficient or less cumbersome. EPA is particularly interested in learning from the regulated community if this approach would aid in reducing monitoring costs and of overcoming matrix interferences. EPA is also particularly interested in learning if this approach would be cumbersome for permitting authorities to administer.

C. Submission Process

Under the system contemplated by this notice, new methods and methods manuals would be submitted to the Office of Science and Technology (OST) which would coordinate proposal of the method(s) under 40 CFR Part 136. The steps involved in developing and preparing a method for proposal are

outlined below. It should be stressed that the preparer should communicate closely with OST throughout this process to ensure that the method will be suitable for proposal at the end of the process.

1. Determination That Method Is New

The preparer should first determine whether the method is a new method or a modification of an existing method under the Agency's method flexibility initiative. The following sources should be consulted in making this determination:

- The FR/CFR reference that implements the system contemplated by this notice [citation].
- Technical Interpretation of Method Flexibility.
- Front-End Techniques that are Candidates for Method Modification under EPA's Method Flexibility Overture.
- Methods Considered Within the Scope of Existing Wastewater Methods Under the EMMC Performance-based Methods System.

2. Method Development

Once it has been determined that a new method is warranted, the method should be developed and documented using the following sources.

- Guidelines and Format for methods to be proposed at 40 CFR Part 136.
- Development of QC Acceptance Criteria.
- The FR/CFR reference that implements the system contemplated by this notice [citation]—Standardized Quality Control.

3. Preliminary Method Submission

Once the method has been written according to a standardized format, the preparer would document plans to validate the method, including a schedule. Section IV.B. Method Validation, should be consulted in planning for appropriate method validation.

4. Method Validation

After writing and initial testing, the preparer would proceed with method validation according to the documented plans. Based on data from the validation study, the method may need to be modified and a further validation study may be required. After completing the validation study(ies), the preparer would write a detailed validation report. EPA may, at a later date, develop the format and requirements for such a report.

5. Preparation of Draft Preamble

Once the method has been properly validated and the method and

validation report are ready for submission, the preparer would develop a draft preamble for proposal of the method at 40 CFR Part 136. If the system contemplated by this notice is found to be desirable, a template for the draft preamble could be provided by EPA to assist the preparer.

6. Submission of Final Method, Validation Report, and Draft Preamble

The final method, validation report, and draft preamble would be sent to EPA. EPA would review these documents and communicate with the preparer regarding questions and to clarify any outstanding issues. EPA would then finalize the preamble, include the appropriate documents in the docket, and submit a proposal for inclusion of the method in 40 CFR Part 136 to the **Federal Register** for public comment.

7. Submission of Proprietary Methods or Methods Containing Proprietary Equipment or Substances

Under several statutes, EPA is prohibited from releasing materials marked as confidential business information (CBI) and has treated analytical methods as CBI when so marked. The Agency believes that the objective of promulgating analytical methods is for the full enjoyment by the public in making determinations of pollutants in the environment. Therefore, EPA believes that proprietary methods should not be included in part 136. However, EPA believes that proprietary equipment or substances used in methods should be maintained as confidential. For example, the liquid phases in gas chromatographic columns are usually known by their confidential name, such as DB-1, SPB-octyl, and Dextsil, although EPA also believes that the nature of proprietary equipment and substances eventually becomes known. EPA seeks a public discussion of whether or not confidential methods should be promulgated at 40 CFR Part 136, and whether the practice of including proprietary equipment and substances in methods should be continued, or if EPA should require identification of these equipment and substances.

V. Harmonization of Methods

A. Harmonization of 40 CFR Part 136 Methods With Other EPA Methods

The methods required for NPDES compliance monitoring are the 40 CFR Part 136 Methods. Although there are many similarities between the technical details of methods from other EPA programs and in other methods, it has

not been acceptable to date to use another method for NPDES monitoring in place of a 40 CFR Part 136 Method. For instance, methods from the Office of Solid Waste SW-846 manual have not been acceptable. However, with the flexibility discussed in this notice, other methods may be permitted, provided that the requirements given in the method and discussed in this notice and its supporting documents are met. This includes the requirement that the determinative step and specificity are equivalent, and that the performance of the method is equal to or better than the performance of the Reference Method. The Reference Method must be a 40 CFR Part 136 method. The other methods can be EPA methods, methods from other organizations, or methods developed by a laboratory or other organization.

In addition to the allowance for use of other methods, if the requirements described in this notice are followed both in letter and in spirit, methods from several of EPA's analytical programs can be fused into a single method acceptable for use in compliance monitoring under the wastewater program and under the EMMC PBMS. For example, using the checklist described in this notice and detailed in the document titled *Methods Considered Within the Scope of Existing Wastewater Methods Under the EMMC Performance-based Methods System (EMMC PBMS Guidance)*, and the analyte lists and QC acceptance criteria in the methods to be fused, EPA Superfund Contract Laboratory Program (CLP) Method OLM02.0, EPA Office of Groundwater and Drinking Water (OGWDW) Method 524.2, and Office of Solid Waste SW-846 Method 8260 can be made acceptable for use in the wastewater program as a front-end modification of Method 624.

The process consists of using the capillary column specified in methods OLM02.0, 524.2, and 8260; testing for all analytes listed in all methods, performing all performance tests in all methods; and meeting the most stringent of the QC acceptance criteria for each test in all methods. For acceptance in the wastewater program under this notice, it would be necessary to perform the standardized QC described above and meet the QC acceptance criteria in Method 624. In addition, and while operating under Method 624, it would be necessary to spike all analytes listed in the permit, and not just the subset of analytes required as the matrix spike in the CLP method. The spike would therefore be specific to the discharge. Alternatively, all analytes listed in Method 624 could be spiked. Further, if the spiked

analytes are not recovered in the normal range (as specified in the QC acceptance criteria in Method 624), it would be necessary to analyze the QC check sample given in Method 624 to demonstrate that a matrix effect had or had not occurred, and that the laboratory was in control. All other performance requirements in Method 624 would also need to be met and the checklists in the EMMC PBMS Guidance would need to be completed to document the use of a front-end modification of Method 624.

B. Standardization of Methods Across Agency Programs

Under the auspices of EPA's EMMC, the various program offices are working to arrive at a single method that transcends Agency programs for the most commonly used methods. The first method being studied is a method for determination of volatile organics by purge and trap gas chromatography/mass spectrometry (GC/MS). If agreement between the program offices can be reached, this method will encompass the analyte lists and quality control requirements in EPA's Drinking Water, Wastewater, Solid Waste, and Remedial programs. Several possible approaches to the development of analyte lists and QC requirements for consolidated methods are being discussed within the Agency. One possible approach is to examine the QC specifications required by each program and include the most stringent requirements in the consolidated methods. Another possible approach is to re-develop analyte lists and QC specifications for the integrated methods; this approach would necessitate interlaboratory studies that could require extensive Agency resources. EPA seeks a public discussion concerning approaches towards integration of Agency methods.

VI. Other Streamlining Issues

A. Standardized Data Elements for Reporting

EPA is also considering standardized data elements for reporting, with an eye toward reporting of results on magnetic media and via electronic means. In certain of its programs, EPA has been accepting analytical data on magnetic media in precisely defined formats for more than 10 years. However, a more generalized format may have broader use. One such format is the Department of Energy Electronic Data Deliverable Master Specification (DEEMS). EPA seeks a public discussion as to whether the Agency should further pursue electronic formats for reporting data

generated using the 40 CFR Part 136 methods.

B. Withdrawal of Outdated Methods

EPA is also considering withdrawal of methods that the Agency believes are obsolete or are no longer used. For example, 40 CFR 136, Table ID, footnote 3 references methods published in 1978 that include thin-layer chromatography (TLC) methods. EPA believes that TLC methods have been outdated by gas chromatography and high performance liquid chromatograph methods for the analytes to which the methods published in 1978 are applied. EPA is therefore considering a careful examination of Tables 1A through 1E of Part 136 for obsolete or outdated methods, and proposing removal of those methods for which newer methods are available.

C. Incorporation by Reference

It is EPA's intention to reduce the number of pages published in the **Federal Register** and the Code of Federal Regulations by incorporating proposed and promulgated methods, respectively, by reference. The approach is intended to reduce the expense of publication in the FR and CFR. EPA also believes that publication in these documents is unnecessary because analytical methods are esoteric in nature and, therefore, not of interest to the general public. In place of publication in the FR and CFR, copies of the methods would be made available through such outlets as the Government Printing Office, the EPA Water Resource Center, the National Technical Information Service, and through meetings such as the Pittsburgh Conference, the annual meeting of the Water Environment Federation, and EPA's Conference on Analysis of Pollutants in the Environment held annually in Norfolk, Virginia. EPA is also exploring distribution of the full text of the proposed and promulgated 40 CFR Part 136 methods on-line.

Consistent with this approach, EPA would also withdraw the 40 CFR 136 Appendix A methods from the CFR and would incorporate these methods by reference, thus reducing the number of pages of material published annually in the CFR by more than 240.

EPA will discuss this removal of methods from publication in the FR and CFR, the use of the Internet for distribution of methods, and other avenues of distribution that could be used to make methods more accessible to interested parties.

VII. Discussion of Information Contained in This Notice

EPA is particularly interested in eliciting constructive discussion that will allow the Agency to incorporate flexibility into existing methods and streamline proposal and promulgation of new methods under 40 CFR Part 136. On the other hand, EPA is interested in compelling reasons why such a program may not work, even with extensive built-in controls to assure that the results produced by modified or new analytical methods are reliable. At this juncture, the floor should be considered open for discussion. EPA looks forward to working with all interested and concerned parties to produce an improved system for methods approval under the 304(h) program.

Dated: September 1, 1995.

Tudor T. Davies,

Director, Office of Science and Technology.

[FR Doc. 95-22608 Filed 9-11-95; 8:45 am]

BILLING CODE 6560-50-P

40 CFR Part 372

[OPPTS-400098; FRL-4972-8]

Zinc Oxide; Toxic Chemical Release Reporting; Community Right-To-Know

AGENCY: Environmental Protection Agency (EPA).

ACTION: Denial of petition.

SUMMARY: EPA is denying a petition to delist zinc oxide from the zinc compounds category subject to the reporting requirements under section 313 of the Emergency Planning and Community Right-to-Know Act of 1986 (EPCRA) and section 6607 of the Pollution Prevention Act of 1990 (PPA). This decision is based on evidence that zinc ion can become available from zinc oxide through several mechanisms and that zinc ion can reasonably be anticipated to be toxic to aquatic organisms.

FOR FURTHER INFORMATION CONTACT: Maria Doa, Petitions Coordinator, 202-260-5997, or e-mail: doa.maria@epamail.epa.gov, for specific information regarding this document. For further information on EPCRA section 313, contact the Emergency Planning and Community Right-to-Know Information Hotline, Environmental Protection Agency, Mail Stop 5101, 401 M St., SW., Washington, DC 20460, Toll free: 800-535-0202, Toll free TDD: 800-553-7672.