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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 122 and 136

[EPA–HQ–OW–2009–1019; FRL–9915–18–OW]

RIN 2040–AC84

National Pollutant Discharge Elimination System (NPDES): Use of Sufficiently Sensitive Test Methods for Permit Applications and Reporting

AGENCY: Environmental Protection Agency.

ACTION: Final rule.

SUMMARY: The Environmental Protection Agency (EPA) is finalizing minor amendments to its Clean Water Act (CWA) regulations to codify that under the National Pollutant Discharge Elimination System (NPDES) program, permit applicants must use ''sufficiently sensitive'' analytical test methods when completing an NPDES permit application and the Director must prescribe that only ''sufficiently sensitive'' methods be used for analyses of pollutants or pollutant parameters under an NPDES permit.

The final rule is based on requirements in the CWA and clarifies existing EPA regulations. It also codifies existing EPA guidance on the use of ''sufficiently sensitive'' analytical methods with respect to measurement of mercury and extends the approach outlined in that guidance to the NPDES program more generally. Specifically, EPA is modifying existing NPDES application, compliance monitoring, and analytical methods regulations. The amendments in this rulemaking affect only chemical-specific methods; they do not apply to the Whole Effluent Toxicity (WET) methods or their use.

DATES: These final regulations are effective September 18, 2014. For judicial review purposes, this final rule is promulgated as of 1:00 p.m. Eastern Time, on September 2, 2014, as provided in 40 CFR 23.2.

ADDRESSES: The record for this rulemaking is available for inspection and copying at the Water Docket, located at the EPA Docket Center (EPA/DC), EPA West 1301 Constitution Ave. NW., Washington, DC 20004. The record is also available via EPA Dockets at *http://www.regulations.gov* under docket number EPA–HQ–OW–2009–1019. The rule and key supporting documents are also available electronically on the Internet at *http://cfpub.epa.gov/npdes/ssmethods.cfm*.

Docket: All documents in the docket are listed in the *www.regulations.gov* index. Some information, however, is not publicly available, e.g., confidential business information (''CBI'') or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is publicly available only in hard copy. Publicly available docket materials are available electronically in *www.regulations.gov* or in hard copy at the Water Docket, EPA Docket Center, EPA West, Room 3334, 1301 Constitution Avenue NW., Washington, DC. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566–1744, and the telephone number for the Water Docket is (202) 566–2426.

FOR FURTHER INFORMATION CONTACT: For additional information, contact Kathryn Kelley, Water Permits Division, Office of Wastewater Management (4203M), Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460; telephone number: (202) 564–7004, email address: *kelley.kathryn@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Potentially Affected Parties

In the NPDES program, point source dischargers obtain permits that are issued by EPA regions and authorized NPDES States, Territories, and Indian tribes (collectively referred to as ''permitting authorities''). These point source dischargers include publicly owned treatment works (POTWs) and various industrial and commercial facilities (collectively referred to as ''NPDES applicants or permittees''). Permitting authorities issue NPDES individual permits after analyzing the information contained in the application and making a determination that the application is ''complete'' under 40 CFR 122.21(e). In the case of a general permit, authorization to be covered by the permit is given if the information submitted demonstrates eligibility for coverage under 40 CFR 122.28. The NPDES permit prescribes the conditions under which the facility is allowed to discharge pollutants into waters of the United States and the conditions that will ensure the facility's compliance with the CWA's technology-based and water quality-based requirements. NPDES permits typically include restrictions on the mass and/or concentration of pollutants [1] that a permittee may discharge as well as requirements that the permittee conduct routine sampling and reporting of various parameters measured in the permitted discharge. In general, NPDES applicants and permittees are required to use EPA-approved methods [2] when measuring the pollutants in their discharges.

The purpose of today's final rule is to codify that where EPA-approved methods exist, NPDES applicants must use sufficiently sensitive EPA-approved analytical methods when quantifying the presence of pollutants in a

[1] Where the term ''pollutant'' is used, it refers to both pollutants and pollutant parameters.

[2] For purposes of this rule, the term ''EPA-approved methods'' refers to methods that have been approved under 40 CFR part 136 or are required under 40 CFR chapter I, subchapter N or O. This includes analytical methods for CWA pollutants developed by EPA, voluntary consensus standards bodies (VCSBs), and other government agencies (such as the U.S. Geological Survey), as well as Alternate Test Procedures (ATPs) developed by commercial method developers for nation-wide use. These methods have been reviewed by EPA and approved for use in compliance monitoring under the CWA. EPA publishes lists of the EPA, VCSB, and other agency methods as well as ATPs that it has found to be acceptable for such use at 40 CFR Part 136, and at 40 CFR Chapter I, subchapters N and O. As a point of clarification, this includes approved ATPs as described in 40 CFR 136.4 and 136.5.

discharge, and the Director [3] must prescribe that only sufficiently sensitive EPA-approved methods be used for analyses of pollutants or pollutant parameters under the permit. The broad universe of entities [4] that would be affected by this final action includes NPDES permitting authorities and municipal and industrial applicants and permittees (Table I–1). This rule does not apply to *indirect dischargers* as defined in 40 CFR 122.2. The impact of this action, however, would only affect those entities that use or allow the use of any EPA-approved analytical methods (for one or more parameters) that are not ''sufficiently sensitive'' to detect pollutants being measured in the discharge.

TABLE I–1—ENTITIES POTENTIALLY REGULATED BY THIS RULE

Category	Examples of potentially affected entities
State, Territorial, and Indian Tribal Governments.	States, Territories, and Indian tribes authorized to administer the NPDES permitting program; States, Territories, and Indian tribes that provide certification under section 401 of the CWA.
Municipalities	POTWs required to apply for or seek coverage under an NPDES individual or general permit and to perform routine monitoring as a condition of any issued NPDES permit.
Industry	Facilities required to apply for or seek coverage under an NPDES individual or general permit and to perform routine monitoring as a condition of any issued NPDES permit.

If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

B. Legal Authority

EPA is issuing today's final rule pursuant to the authority of sections 301, 304(h), 308, 402(a), and 501(a) of the CWA [33 U.S.C. 1311, 1314(h), 1316, 1318, 1342(a), 1343, and 1361(a)]. Section 301(a) of the CWA prohibits the discharge of any pollutant except in compliance with an NPDES permit issued under section 402 of the act. Section 402(a) of the CWA authorizes the Administrator to issue permits that require a discharger to meet all the applicable requirements under sections 301, 302, 306, 307, 308, and 403. Section 301(b) of the CWA further requires that NPDES permits include effluent limitations that implement technology-based standards and, where necessary, water quality-based effluent limitations (WQBELs) that are as stringent as necessary to meet water quality standards. With respect to the protection of water quality, NPDES permits must include limitations to control all pollutants that the NPDES permitting authority determines are or might be discharged at a level that ''will cause, have the reasonable potential to cause, or contribute to an excursion above any state water quality standard,'' including both narrative and numeric criteria [40 CFR 122.44(d)(1)(i)]. If the Director determines that a discharge causes, has the reasonable potential to cause, or contributes to such an excursion, the permit must contain WQBELs for the pollutant [40 CFR 122.44(d)(1)(iii)]. Section 402(a)(2) of the CWA requires EPA to prescribe permit conditions to ensure compliance with requirements, ''. . . including conditions on data and information collection, reporting and such other requirements as [the Administrator] deems appropriate.'' Thus, a prospective permittee might need to measure various pollutants in its effluent at two stages: First, at the permit application stage so that the Director can determine what pollutants are present in the applicant's discharge and the amount of each pollutant present and, second, to quantify the levels of each pollutant limited in the permit to determine whether the discharge is in compliance with the applicable limits and conditions.

Section 304(h) of the CWA requires the Administrator of 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 401of this Act] or permit application 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 this function under [the act].'' EPA generally has codified its test procedure regulations (including analysis and sampling requirements) for CWA programs at 40 CFR part 136, although some requirements are codified in other parts (e.g., 40 CFR chapter I, subchapters N and O).

The Director is required under 40 CFR 122.21(e) to determine when an NPDES permit application is complete. Moreover, the Director shall not begin processing an application for an individual permit until the applicant has fully complied with the application requirements for that permit [40 CFR 124.3(a)(2)]. Under 40 CFR 122.21(g)(13), applicants are required to provide to the Director, upon request, such other information as the Director may reasonably require to assess the discharge. Finally, 40 CFR 122.41(j)(1) requires NPDES permits to include a standard condition specifying that ''samples and measurements taken for the purpose of monitoring shall be representative of the monitored activity.''

Among other things, section 308 of the CWA authorizes EPA to require owners or operators of point sources to establish records, conduct monitoring activities, and make reports to enable the permitting authority to determine whether there is a violation of any prohibition or any requirement established under provisions including section 402 of the CWA. Under sections 308(c) and 402(b)(2)(A), a state's authorized NPDES program must have authorities to inspect, monitor, enter, and require reports to at least the same extent as required in section 308.

As summarized above, the legal requirements and authorities exist for EPA to require NPDES applicants and permittees to use sufficiently sensitive EPA-approved analytical methods when quantifying the presence of pollutants in a discharge and to require the Director to require and accept only such data.

II. Background

Multiple analytical test methods exist for many pollutants regulated under the CWA. Therefore, EPA has generally

[3] The term ''Director'' refers to the permitting authority. See definition at 40 CFR 122.2.

[4] Although terms such as ''authorities,'' ''applicants,'' and ''permittees'' imply individuals, EPA uses these terms to refer to entities. For example, EPA uses the term ''NPDES permitting authorities'' to mean the EPA Regions, States, Territories, and Indian tribes granted authority to implement and manage the NPDES program. EPA uses the term ''NPDES applicants'' or ''NPDES permittees'' to mean facilities that have applied for, sought coverage under, or been issued an NPDES individual or general permit.

approved multiple methods for CWA pollutants under 40 CFR part 136 and 40 CFR chapter I, subchapters N and O. Some of the approved analytical test methods have greater sensitivities and lower minimum levels [5] [6] or method detection limits (MDLs) [7] than other approved methods for the same pollutant. This situation often occurs because of advances made in instrumentation and in the analytical protocols themselves. Many metals and toxic compounds (for example, mercury) have an array of EPA-approved methods, including some methods that have greater sensitivities and lower minimum levels than the others.

Although EPA has approved multiple analytical methods for individual pollutants, the Agency has historically expected that applicants would select from the array of available methods a specific analytical method that is sufficiently sensitive to quantify the presence of a pollutant in a given discharge. EPA has not expected that NPDES permit applicants would select a method with insufficient sensitivity, thereby masking the presence of a pollutant in their discharge, when an EPA-approved sufficiently sensitive method is available. Further, EPA anticipated that NPDES permitting authorities would specify an EPA-approved method in an NPDES permit where the Director determined that a particular analytical method was needed to provide meaningful results relative to the permit limit. EPA believes that the authority to prescribe a specific analytical method in an NPDES permit exists under the current regulations. However, some state permitting authorities expressed concern that this authority was not explicit in current regulations, thus limiting states' ability to prescribe an appropriate analytical method where needed to assess compliance with permit limits. This rule requires that, where EPA-approved methods exist, NPDES applicants must use sufficiently sensitive EPA-approved analytical methods when quantifying the presence of pollutants in a discharge and that the Director must prescribe that only sufficiently sensitive EPA-approved methods be used for analyses of pollutants or pollutant parameters under the permit.

EPA and state permitting authorities use data from the permit application to determine whether pollutants are present in an applicant's discharge and to quantify the levels of all detected pollutants. These pollutant data are then used to determine whether technology- or water quality-based effluent limits are needed in the facility's NPDES permit. It is critical, therefore, that applicants provide data that have been measured at levels that will be meaningful to the decision-making process. Among other things, data must be provided that will enable the Director to make a sound ''reasonable potential'' determination and, if necessary, establish appropriate water quality-based permit limits. The same holds true for monitoring and reporting relative to permit limits established for regulated parameters. The intent is for applicants and permittees to use analytical methods that are capable of detecting and measuring the pollutants at, or below, the respective water quality criteria or permit limits.[8]

For example, in 2002 and 2007 EPA published two new analytical methods for mercury that were several orders of magnitude more sensitive than previously available methods. In addition, a number of states have set water quality criteria for mercury that are below the detection levels of the older methods for mercury that EPA approved prior to 2002. Unlike the previous methods, the new methods are capable of measuring whether effluent samples are above or below the current water quality criteria. In 2007 EPA addressed this issue with respect to mercury in a memorandum titled ''Analytical Methods for Mercury in NPDES Permits,'' from James A. Hanlon, Director of EPA's Office of Wastewater Management, to the Regional Water Division Directors. This memorandum is available at *http://www.epa.gov/npdes/pubs/mercurymemo_analyticalmethods.pdf*. The memorandum explains EPA's expectation that ''All facilities with the potential to discharge mercury will provide with their NPDES permit applications monitoring data for mercury using Method 1631E or another sufficiently sensitive EPA-approved method. Accordingly, EPA strongly recommends that the permitting authority determine that a permit application that lacks effluent data analyzed with a sufficiently sensitive EPA-approved method such as Method 1631E, is incomplete unless and until the facility supplements the original application with data analyzed with such a method.''

Following issuance of the 2007 memorandum, EPA determined that the NPDES permit application regulations at 40 CFR 122.21 and the NPDES permit monitoring requirements at 40 CFR 122.44 should be revised to ensure that, where EPA-approved methods exist, applicants use sufficiently sensitive EPA-approved analytical methods when quantifying the presence of pollutants in a discharge and that Directors prescribe that only sufficiently sensitive EPA-approved methods be used to perform sampling and analysis for all pollutants, not just mercury. Therefore, in this rulemaking, EPA is revising the regulations to extend the requirement to use sufficiently sensitive EPA-approved analytical test methods, where they exist, to all pollutants and establish criteria for what qualifies as a ''sufficiently sensitive'' method.

This final rule requires that NPDES applicants must use sufficiently sensitive EPA-approved analytical methods, where they exist, when submitting information required by a permit application quantifying the presence of pollutants in a discharge. If the applicant does not provide data using a sufficiently sensitive EPA-approved analytical method, the Director may determine that the application is ''incomplete'' per 40 CFR 122.21(e).The Director may require that the applicant provide new screening data obtained using a sufficiently sensitive EPA-approved analytical method before making a completeness determination and moving forward with permit development. The final rule also requires that, as a condition of permit development, to assure compliance with permit limitations the permit shall include requirements to monitor according to sufficiently sensitive EPA-approved methods, where they exist.

[5] The term ''minimum level'' refers to either the sample concentration equivalent to the lowest calibration point in a method or a multiple of the method detection limit (MDL). Minimum levels may be obtained in several ways: They may be published in a method; they may be sample concentrations equivalent to the lowest acceptable calibration point used by a laboratory; or they may be calculated by multiplying the MDL in a method, or the MDL determined by a lab, by a factor. [See: (A) 40 CFR 136, appendix A, footnotes to table 2 of EPA Method 1624 and table 3 of EPA Method 1625 (49 FR 43234, October 26, 1984); (B) 40 CFR 136, section 17.12 of EPA Method 1631E (67 FR 65876–65888, October 29, 2002); (C) 61 FR 21, January 31, 1996; and (D) ''Analytical Method Guidance for the Pharmaceutical Manufacturing Point Source Category,'' EPA 821–B–99–003, August 1999].

[6] For the purposes of this rulemaking, EPA is considering the following terms related to analytical method sensitivity to be synonymous: ''quantitation limit,'' ''reporting limit,'' ''level of quantitation,'' and ''minimum level.''

[7] The MDL is determined using the procedure at 40 CFR Part 136, appendix B. It is defined as the minimum concentration of a substance that can be measured and reported with 99 percent confidence that the analyte concentration is greater than zero and is determined from analysis of a sample in a given matrix containing the analyte.

[8] To address this situation some state permitting authorities have developed a list of monitored parameters and prescribed a required minimum level that must be achieved for each parameter as a part of their state regulations or policy.

Specifically, where an EPA-approved analytical method exists that would provide quantifiable results necessary to assess compliance with a permit limit and the permit allows monitoring to be conducted using different analytical methods that, although approved, would fail to produce data necessary to assess compliance, the permit would be inconsistent with the NPDES permitting requirements of 40 CFR 122.44(i).

EPA is defining the term ''sufficiently sensitive'' in two sections of the NPDES regulations: At 40 CFR 122.21(e) (Completeness), as a new subsection (3), and at 40 CFR 122.44(i)(1)(iv) (Monitoring Requirements). EPA is also modifying 40 CFR 136.1 (Applicability) by adding a new paragraph (c), which is simply a cross-reference to the changes being promulgated in 40 CFR 122.21(e)(3) and 40 CFR 122.44(i)(1)(iv). The new and revised sections indicate that an EPA-approved method is sufficiently sensitive where:

A. The method minimum level is at or below the level of the applicable water quality criterion or permit limitation for the measured pollutant or pollutant parameter; or

B. In the case of permit applications, the method minimum level is above the applicable water quality criterion, but the amount of the pollutant or pollutant parameter in a facility's discharge is high enough that the method detects and quantifies the level of the pollutant or pollutant parameter in the discharge; or

C. The method has the lowest minimum level of the EPA-approved analytical methods.

The requirement to use a ''sufficiently sensitive'' EPA-approved method does not apply where no EPA-approved method exists. When no analytical method is approved under 40 CFR part 136 or required under subchapter N or O, and a specific method is not otherwise required by the Director, an NPDES applicant may use any suitable method; however, the applicant shall provide a description of the method.

The first two criteria, A and B, in the sufficiently sensitive definition address situations in which EPA has approved multiple methods for a pollutant and some of those approved methods have greater sensitivities and lower minimum levels than others. In this situation, the applicant or permitting authority may select a method based on the minimum level published in the EPA-approved method, where available, or using a derived minimum level. As noted in footnote 4, the minimum level may be explicitly listed in some EPA-approved methods. Where this is the case, the applicant may reference the published minimum level when determining whether a method selected to provide data for their permit application is sufficiently sensitive. Where EPA has included a minimum level for a pollutant in a specific method, it reflects the minimum level obtained in a multi-laboratory study of the new method in a wide variety of matrices, many of which EPA selects due to their complex nature. EPA acknowledges that complex matrices exist and provides flexibility and suggestions for ways to mitigate interferences in such instances, often within the published method for a specific pollutant. EPA's experience is that many laboratories find solutions to address difficult matrices and are able to achieve the published minimum level within the required quality assurance specifications. However, applicants have always had the option of calculating a matrix-specific method detection limit (MDL). Extreme matrices may necessitate the use of an elevated sample specific minimum level, in which case the laboratory should be able to show that a reasonable effort (e.g., published cleanup procedures) was attempted to achieve as low a minimum level as possible for those samples. The use of sample or matrix specific minimum levels rather than the published levels has always been an available option, and consistent with that flexibility, use of a matrix-specific minimum level may sometimes be necessary when determining which methods are sufficiently sensitive.

For EPA-approved methods that do *not* explicitly list minimum levels, the applicant can derive the minimum level from either the concentration of the lowest calibration standard in methods that dictate the concentrations of such standards, or as a multiple of the MDL or similar statistically derived detection limit concept. When the method dictates, or recommends, the concentration of the lowest calibration standard, that concentration can be converted to a minimum level by considering the weights and/or volumes of the sample and all of the intermediate preparation and analysis steps in the method. If a method provides a literature MDL for the matrix of interest, that MDL value can be used to estimate the minimum level as 10 times the standard deviation of the replicate measurements used to determine the MDL according to 40 CFR part 136, appendix B. However, MDLs are inherently method- and laboratory-specific, so whenever a permittee is contracting a laboratory for NPDES work, it is prudent to obtain that laboratory's MDL and compare it to the published MDL to ensure that both their MDL and their minimum level are appropriate for the intended application.

The third criterion, C, of the definition addresses situations in which none of the EPA-approved methods for a pollutant can achieve the minimum levels necessary to assess reasonable potential or to monitor compliance with a permit limit. In these situations, applicants or permittees must use the method with the lowest minimum level among the EPA-approved methods for the pollutant, and this method would meet the definition of sufficiently sensitive.

As explained above, the requirement to use a ''sufficiently sensitive'' EPA-approved method does not apply where no EPA-approved methods exist. The final rule addresses these situations, for permit applicants, where no approved analytical method exists under 40 CFR part 136 or is required under subchapter N or O, and one is not otherwise required by the Director. In such situations, an applicant may use any suitable method but shall provide a description of the method. With respect to pollutant limits in permits, where an EPA-approved analytical method does not exist, monitoring shall be conducted in accordance with a test procedure specified in the permit.

EPA recognizes that other factors beyond the minimum level or MDL can also be important in determining method performance, including a method's resolution, accuracy, and precision. Where there are no EPA-approved methods, this rule does not affect how those other factors are considered in selecting a method. Rather, the rule notes that permit applicants may consider these other factors when selecting a suitable method where no EPA-approved method exists.

For EPA-approved methods, however, these factors have already been considered during the method validation and approval process. As explained above, EPA evaluates method performance in a wide variety of wastewater matrices and approves those methods that have sensitivity, precision and accuracy that are appropriate for wastewater compliance monitoring. 40 CFR 136.6 also allows flexibility to tailor approved methods to more challenging wastewater matrices or overcome methodological problems. Based on data and information provided to EPA by analytical laboratories, EPA finds that experienced laboratories are often capable of achieving minimum levels below those published with a

method while maintaining the precision and accuracy specified in the method.

EPA acknowledges that while rare, methodological problems may exist that could affect the determination of a ''sufficiently sensitive'' method. In such rare situations, the Director may consider additional technical factors when determining whether the method is still ''sufficiently sensitive.'' Specifically, where the permit applicant or permittees can demonstrate to the Director that despite a good faith effort to overcome these methodological problems due to challenging wastewater matrices, either (1) the method's minimum level is higher than originally anticipated, or (2) the method results no longer meet the methods quality assurance/quality control (''QA/QC'') specification, the Director may take these factors into account when determining whether the permit applicant has met the requirements to use a ''sufficiently sensitive'' method or in prescribing a ''sufficiently sensitive'' method in the permit. In the first situation, the matrix or sample-specific minimum level should be used to evaluate which of the EPA-approved methods is ''sufficiently sensitive.'' In the second situation, if the method's results are no longer consistent with the QA/QC specifications, then the method is not performing adequately and a ''sufficiently sensitive'' method should be selected from the remaining EPA-approved methods. In either case, the permit applicant or permittee is responsible for demonstrating that a published minimum level is unachievable or a reasonable effort was applied to bring the original sufficiently sensitive method within the QA/QC specifications in the given matrix before selecting another EPA-approved method (e.g., cleanup procedures, dilution when appropriate, etc.).

Additionally, where a technology-based requirement is specified as ''zero discharge'' or ''no detect,'' the permitting authority may take into account the sensitivity of the method used to establish the requirement when determining if a method is ''sufficiently sensitive.'' EPA recognizes that if a more sensitive method is approved after such a requirement has been established, its use may be inconsistent with the technological basis of the original requirement. In situations where a technology-based requirement reflects a technology that eliminates the discharge of the subject pollutant altogether, the newer sensitive method is appropriate. However, where a technology-based limit reflects a technology that may not achieve the minimum level of the newer more sensitive method, the Director may determine that the method on which the requirement was originally based is ''sufficiently sensitive'' to determine compliance, as understood at the time the requirement was established.

For both EPA-approved methods and non-EPA-approved methods, EPA's understanding of standard practice is that if an applicant/permittee or laboratory has questions regarding the suitability of a specific method in a given situation, or has technical questions on its use, it will consult with its permitting authority. EPA has the same expectations in connection with today's rulemaking for questions specifically about which methods are sufficiently sensitive. The permitting authority continues to have the ultimate responsibility for determining whether an NPDES application is complete (40 CFR 122.21(e)) and establishing permit conditions, including monitoring and reporting requirements (40 CFR 122.44(i)).

The amendments in this rulemaking affect only chemical-specific methods; they do not apply to the Whole Effluent Toxicity (WET) methods or their use. Note that existing EPA regulations (40 CFR 122.44(d)(1)(ii)) and policy require permit writers to take into account the sensitivity of the species to toxicity testing when evaluating whole effluent toxicity. EPA has interpreted this provision as directing the permitting authority to develop criteria and limits based upon the most sensitive test species to ensure that the most sensitive species and all less sensitive species will be protected.

III. Summary of Public Comments and EPA's Response

On June 23, 2010, EPA proposed changes to the existing NPDES regulations (75 FR 35712) and requested comments from the public. EPA received 25 comment letters. The majority of the comments came from publicly owned treatment works and industry organizations, but EPA also received comments from laboratories, and state and federal agencies. The majority of comments covered the following categories: Implementation and technology; administration and timing; and burden. The complete list of comments and responses is available in the record of this rulemaking.

A. Implementation

1. Effect of the Rule on Current Practices

EPA received several comments that indicated the approach outlined in the proposed rule would force applicants and permittees to make decisions regarding the selection of an appropriate method without adequate information upon which to base a decision. Specifically, commenters indicated that issues related to the definition of the method minimum level would make this rule difficult to implement and that method sensitivity should not be the sole factor in deciding which method should be used in the permitting process. They indicated that there are other factors including accuracy, precision, selectivity, and whether the method has been validated that should be considered.

In response, EPA notes that applicants for NPDES permits have always needed to make decisions regarding which EPA-approved methods are the most appropriate for use when performing the screening analyses required under the various permit application regulations at 40 CFR 122.21. Similarly, NPDES permitting authorities, even before today's rulemaking, have had to consider which of the EPA-approved methods are the most appropriate for permittees to use to meet their monitoring and reporting requirements under an NPDES permit. Today's rule does not change the basic NPDES permit application or permit issuance process. Under 40 CFR 122.21, permittees seeking permit renewal or new applicants must provide the Director with adequate information to determine whether an NPDES application is complete. Once the Director makes this determination, the Director determines the applicable permit requirements, including any sampling or monitoring that must be taken that is ''representative of the monitored activity.'' See 40 CFR 122.41(j)(1). The effect of today's final rulemaking is to codify that where EPA-approved methods exist, only ''sufficiently sensitive'' EPA-approved methods may be used in connection with permit applications and to conduct monitoring and reporting under a permit.

To determine whether an EPA-approved analytical method is ''sufficiently sensitive'' in any particular case, NPDES applicants/permittees and permit authorities should use the best information available on what the minimum level is for the method, and EPA believes that in general a method's accurate minimum level will be readily ascertainable. Where the minimum level is explicitly listed in the EPA-approved method, applicants may reference the published minimum level when determining whether a method selected to provide data for their permit application is sufficiently sensitive. Alternatively, applicants have always had the option of providing matrix-specific method detection limits and

minimum levels rather than the published minimum levels, and nothing in today's rule changes that flexibility, including with respect to selecting a sufficiently sensitive EPA-approved method. For these cases the laboratory should be able to show that a reasonable effort (e.g., published cleanup procedures) was attempted to achieve as low a minimum level as possible for those samples. For EPA-approved methods that do *not* explicitly list minimum levels, the minimum level can be obtained or derived by the applicant or permitting authority. Indeed, many permitting authorities have developed guidance, policies or regulations that establish minimum levels for various methods, or specify specific methods to be used by applicants and permittees. Where applicable, these policies and regulations will continue to affect method selection, although at the same time, states must ensure that such policies and regulations conform with the criteria established in today's rulemaking that, where they exist, only ''sufficiently sensitive'' EPA-approved methods are being used when completing an NPDES permit application and when performing sampling and analysis pursuant to monitoring requirements in an NPDES permit. If the applicant does not provide data using a sufficiently sensitive EPA-approved analytical method where one exists, the Director may determine that the application is ''incomplete'' per 40 CFR 122.21(e). The Director may require that the applicant provide new screening data obtained using a sufficiently sensitive EPA-approved analytical method before making a completeness determination and moving forward with permit development. Thus, to avoid having the permitting authority reject data provided in an application because the data were not collected by means of a ''sufficiently sensitive'' method, the NPDES applicant should work closely with the permitting authority prior to conducting the required analyses. In addition, the permitting authority must ensure the permit includes a requirement to use a sufficiently sensitive EPA-approved analytical test method, where one exists, where necessary to perform sampling and analysis, consistent with 40 CFR 122.41(j) and 122.44(i).

2. Development of New or Alternate Test Procedures

EPA received several comments that indicated the proposed rule would require the development of new analytical methods where no EPA-approved methods exist or where existing EPA-approved methods would not quantify the pollutant concentration at or below the level of the criterion or permit limit. Other commenters indicated that the rule would alter the existing requirements for developing Alternate Test Procedures under 40 CFR part 136. EPA has modified the proposal to address these comments, as explained below.

EPA has modified the proposed language for this final rule so that it does not change existing regulatory requirements with respect to unapproved methods. Where no EPA-approved analytical methods exist, an applicant will need to select a method from another source of available analytical methods (e.g., Standard Methods for the Examination of Water and Wastewater) to measure that pollutant or pollutant parameter. Today's final rule does not require the applicant to develop new methods. The situation in which there are no EPA-approved methods is uncommon because there are EPA-approved methods for most pollutants or pollutant parameters screened and regulated under the NPDES program. Under the existing regulations at 40 CFR 122.21(g)(7), the NPDES applicant has the flexibility to use any suitable analytical method when no EPA-approved analytical method exists for that pollutant or pollutant parameter. Additionally, under the existing regulations at 40 CFR 122.44(i)(1)(iv), the NPDES permitting authority specifies a method in the permit when there is no EPA-approved method.

Where EPA-approved methods exist, but none of the available methods will quantify the pollutant concentration at or below the level of the criterion or permit limit, today's rulemaking does not require the development of any new analytical methods. However, in this situation, the rule will now require the use of the most sensitive of the EPA-approved methods.

Finally, today's rulemaking does not alter any of the existing requirements related to the development or approval of alternative test procedures under 40 CFR 136.4 and 136.5.

3. Consideration of Matrix Effects in Selecting a Sufficiently Sensitive Method

EPA received several comments that indicated the approach outlined in the proposed rule would force applicants and permittees to make decisions regarding the selection of an appropriate method without adequate information upon which to base a decision. Specifically, commenters indicated that issues related to the definition of the method minimum level would make this rule difficult to implement and that method sensitivity should not be the sole factor in deciding which method should be used in the permit process. They believe there are other critical factors including accuracy, precision, selectivity, and whether the method has been validated.

In response, as noted above, EPA has clarified that the requirement to use a ''sufficiently sensitive'' EPA-approved method does not apply where no EPA-approved method exists. EPA agrees that other factors beyond the minimum level can also be important in determining method performance, including a method's selectivity, resolution, accuracy, and precision. EPA has added language in the rule text that clarifies where no EPA-approved methods exist, permit applicants may consider these other factors, in conjunction with sensitivity, when selecting an appropriate method.

For EPA-approved methods, however, these factors have already been considered during the method validation and approval process. As explained above, EPA evaluates method performance in a wide variety of wastewater matrices and approves those methods that have selectivity, sensitivity, precision and accuracy that are appropriate for wastewater compliance monitoring. 40 CFR 136.6 also allows flexibility to tailor approved methods to more challenging wastewater matrices. EPA notes that applicants have always had the option of providing matrix or sample-specific minimum levels rather than the published levels and nothing in today's rule changes that flexibility, including with respect to selecting a sufficiently sensitive EPA-approved method. For these cases the laboratory should be able to show that a reasonable effort (e.g., published cleanup procedures) was attempted to achieve as low a minimum level as possible for those samples.

If the most sensitive method listed in 40 CFR Part 136 is not performing adequately in a given wastewater matrix (e.g., with regard to sensitivity, accuracy, and precision), several options are available and should be pursued. Dilution is often a good option if it does not drive the sample specific minimum level above the permit requirements. Cleanup procedures included in the method can also be utilized. If those cleanups do not prove adequate for a particular matrix, the analyst should consult ''Solutions to Analytical Chemistry Problems with Clean Water Act Methods,'' EPA 821–R–07–002 (or more recent revisions) to

determine if another cleanup procedure may be appropriate. If a solution is still not apparent, the permittee should consult EPA or the permitting authority.

Based on data and information provided to EPA by analytical laboratories, EPA finds that experienced laboratories are often capable of achieving minimum levels below those published with a method while maintaining the precision and accuracy specified in the method. However, EPA acknowledges that while rare, situations may exist where a method cannot perform adequately in a specific matrix. In such rare situations, the Director may consider additional technical factors when determining whether the method is still ''sufficiently sensitive.'' Specifically, where the permit applicant or permittees can demonstrate to the Director that despite a good faith effort to overcome these methodological problems due to challenging wastewater matrices, either (1) the method's minimum level is higher than originally anticipated, or (2) the method results no longer meet the methods QA/QC specification, the Director may take these factors into account when determining whether the permit applicant has met the requirements to use a ''sufficiently sensitive'' method or in prescribing a ''sufficiently sensitive'' method in the permit. In the first situation, the matrix or sample-specific minimum level should be used to evaluate which EPA-approved method is ''sufficiently sensitive.'' In the second situation, if the method's results are no longer consistent with the QA/QC specifications, then the method is not performing adequately and a ''sufficiently sensitive'' method should be selected from the remaining EPA-approved methods. In either case, the permit applicant or permittee is responsible for demonstrating that a published minimum level is unachievable or a reasonable effort was applied to bring the original sufficiently sensitive method within the QA/QC specifications in the given matrix before selecting another EPA-approved method (e.g., cleanup procedures, dilution when appropriate, etc.). To illustrate the type of situations where this provision would be appropriate, EPA provides two examples below.

EPA received comments about the situation where there are multiple EPA-approved methods for an organic pollutant and the methods employ different technologies (i.e., gas chromatography (GC) and gas chromatography/mass spectrometry (GC/MS)). These commenters raised concern that, in some instances, while the GC method may provide a lower detection limit, the GC/MS method provides a greater degree of confidence in the correct identification of the regulated parameter. As explained above, this is not an issue if the laboratory has demonstrated that it can achieve a minimum level for GC/MS that is lower than the NPDES permit limit for the regulated parameter, in which case GC/MS would be considered ''sufficiently sensitive.'' EPA agrees that GC/MS is more selective than GC, but several options are available to remove the interferences from difficult matrices before using a dual-column GC method (e.g., solid-phase extraction as a cleanup procedure, Florisil cleanup, alumina cleanup, sulfur removal with copper or TBA sulfite, gel permeation chromatography, etc.). Generally, a result from a dual-column GC method would only be questioned if the chromatograms from the two columns did not yield similar numerical results or if the chromatograms contained many extraneous peaks that suggest interferences are present. If the permit applicant or permittee is still concerned that the peaks may be caused by a different contaminant, and the GC method provides a false positive result, the permit applicant or permittee could use a GC/MS to confirm the presence of the contaminant. However, since the GC/MS is less sensitive, it may not be able to confirm low-level dual column GC results. The more sensitive GC/MS method options (e.g., larger sample volume, smaller final extract volume, selected ion monitoring techniques, or high resolution GC/MS) may be necessary to prove whether the dual column GC result is a false positive. The permittee should also consult with EPA and/or its permitting authority for potential solutions. In this case, if the permittee has exhausted all practical options (e.g., solid-phase extraction as a cleanup procedure, Florisil cleanup, alumina cleanup, sulfur removal with copper or TBA sulfite, gel permeation chromatography, etc.) and has documentation to demonstrate that the dual-column GC creates false positive results for that specific matrix, then the Director would appropriately approve the selection of a different EPA-approved method that would then be considered a sufficiently sensitive method (e.g., GC/MS).

As another example, EPA also received comments specific to Method 1631 for mercury. These commenters noted that use of the ''clean'' sampling methods associated with this method to minimize potential contamination from the sampling technique itself is not possible in many industrial settings. They noted that EPA's documentation of the sampling technique acknowledges it is not intended for treated and untreated discharges from industrial uses. EPA notes that since approval of this method and the associated clean sampling techniques, these techniques have been successfully used in some industrial settings. For example, sewage treatment plants accepting industrial wastewater have successfully eliminated permit exceedances for mercury as measured by Method 1631 by employing the clean sampling procedures. Where the permittee has documentation that clean sampling techniques cannot be adopted for the site-specific application, the Director would appropriately approve the selection of a different EPA-approved method that meets the definition of a sufficiently sensitive method (e.g., the one with the lowest minimum level of the remaining EPA-approved methods). If the ambient level of mercury contamination at the site is too high to use clean sampling methods, then using a less sensitive EPA-approved method can meet the definition of a sufficiently sensitive method.

Another commenter raised concerns specific to Method 1631. They questioned the method's suggestion to minimize laboratory contamination by soaking laboratory air filters in gold chloride solution so that mercury in incoming air will amalgamize with the filter's gold. This commenter questioned whether or not it was EPA's expectation that laboratories go to such lengths to employ such a sufficiently sensitive method where required under this rule. EPA notes the procedure described by the commenter is only a suggestion if laboratories are having problems with laboratory contamination. There are now many laboratories that perform Method 1631 without undue difficulty. In this case, where necessary to meet the definition of ''sufficiently sensitive'' in today's final rule, EPA would expect that the permittee use Method 1631, since the permittee should send their sample to a laboratory that can demonstrate it has control over sources of mercury within its own environment.

Finally, where a technology-based requirement is specified as ''zero discharge'' or ''no detect,'' the permitting authority may take into account the sensitivity of the method used to establish the requirement when determining if a method is ''sufficiently sensitive.'' EPA recognizes that if a more sensitive method is approved after such a requirement has been established, its use may be inconsistent with the technological basis of the original requirement. In situations where a

technology-based requirement reflects a technology that eliminates the discharge of the subject pollutant altogether, the newer sensitive method is appropriate. However, where a technology-based limit reflects a technology that may not achieve the minimum level of the newer more sensitive method, the Director may determine that the method on which the requirement was originally based is ''sufficiently sensitive'' to determine compliance, as understood at the time the requirement was established.

4. Report of the Federal Advisory Committee on Detection and Quantitation Approaches and Uses in Clean Water Act Programs

EPA received a number of comments that identified concerns that the proposed rule uses terms, such as minimum level, that are not defined in new or existing regulations. Commenters also indicated that the proposed rule fails to address a variety of issues regarding detection and quantitation that were raised in the Report of the Federal Advisory Committee on Detection and Quantitation Approaches and Uses in Clean Water Act Programs. EPA agrees that there are a variety of related issues raised in the aforementioned report, yet notes that the members of the Federal Advisory Committee (FAC) were unable to reach consensus over several key issues in the report. While several of these issues, such as the definition of minimum level, are discussed in today's rulemaking, applicants and permitting authorities must still, on a regular and ongoing basis, choose which of the available analytical methods are most appropriate for use when screening effluent for permit applications and as part of permit conditions. This has always been the case, regardless of today's rulemaking.

EPA believes that the requirements of the rule are adequately described and can be implemented without having to address the myriad of issues considered by the FAC. For today's rulemaking, EPA is not redefining or establishing new method detection limits (MDLs) or minimum levels, developing new procedures for determining detection or quantitation, or maintaining a clearinghouse on detection and quantitation issues. EPA considers such issues to be outside the scope of today's rulemaking.

5. Other Factors Affecting Selection of Analytical Methods

EPA received several comments that expressed concern that the rule would require the use of only the most sensitive available method, and that other factors such as geographical isolation or unique sample collection constraints might preclude the use of certain available methods. Some comments also expressed concerns regarding the availability of laboratories qualified to conduct some of the more sensitive analytical methods, particularly where the state requires applicants and permittees to use laboratories certified by the state to conduct analyses.

EPA is not requiring the use of any specific analytical technology or practice over others; only that the selected EPA-approved method is sufficiently sensitive. EPA expects that, in general, factors such as geographical isolation, or unique sampling collection constraints would not preclude the selection of a sufficiently sensitive method. The definition does not require the use of the most sensitive EPA-approved method available, so long as a less sensitive approved method still meets the criteria for being ''sufficiently sensitive.'' In cases where factors beyond a facility's control render the use of a particular method infeasible, such as extreme geographical isolation, the permitting authority could consider such factors in deciding which method best meets the definition of ''sufficiently sensitive.'' EPA expects such situations would be rare.

Issues related to sampling procedures, such as holding times, are frequently prescribed by the test procedures in 40 CFR Part 136, and may be contingent on the unique physical, chemical, and biological characteristics of the discharge. Standard practice has been and continues to be that if an applicant/permittee or laboratory has questions regarding the appropriateness of using a specific method in a given situation, or has technical questions on its use, it should consult with its permitting authority prior to conducting monitoring.

B. Administration and Timing

EPA received a few comments regarding the effect of the rule on recordkeeping and reporting requirements. The rule does not change existing recordkeeping and reporting requirements at 40 CFR 122.21(p), 122.41(j) and 122.48. The permitting authority, however, has discretionary authority to require its applicants or permittees to provide information under the latter two provisions. In addition, a few comments asked whether the rule alters the terms or conditions of existing permits. The rule itself does not modify the terms or conditions of existing NPDES permits. If, under the requirements of today's rulemaking, a change needs to occur in the analytical methods specified in an existing permit, that change would occur at the time of permit renewal, or it could occur through a permit modification under the procedures of 40 CFR Part 124, if the permitting authority determined that such a modification was appropriate.

EPA received a few comments regarding whether existing data, if collected using insufficiently sensitive methods, will be acceptable for submission with an application for permit renewal. NPDES application monitoring data that is collected after the effective date of the rule, or, if applicable, after an authorized state has revised its regulations to adopt the provisions of the rule,[9] must be based on the use of sufficiently sensitive test methods. However, the rule does not negate the existing requirement for applicants to submit data from previous years, even where these data may have been collected using methods that did not conform to the sufficiently sensitive criteria established in this rule. Based on all of the data submitted with the permit application, the permitting authority will determine whether it has information adequate to develop an NPDES permit. Where the permitting authority determines that data was collected using insufficiently sensitive methods, it may choose to disregard this information and accept only data collected employing sufficiently sensitive EPA-approved methods. In addition, even prior to the effective date of today's rulemaking, the permitting authority has the authority under the existing NPDES regulations to request additional data from applicants where insufficient data is provided with the application before considering an application complete.

EPA received a few comments pertaining to the rule's impact on indirect dischargers. The rule affects only direct dischargers (those applying for an individual NPDES permit) and state/EPA NPDES permitting authorities. The rule does not apply to indirect dischargers. POTWs with approved pretreatment programs may at their discretion (as authorized by their local ordinances and regulations) require their indirect dischargers to achieve specific minimum levels when performing analyses or may require the use of specific methods to enable them to better characterize contributions into their system. Where a state or EPA is the

[9] Authorized NPDES states have up to one year following rule issuance to revise their own regulations to conform to the requirements of this rule. Authorized NPDES states have up to two years to conform to the rule's requirements if they must make statutory changes.

pretreatment Control Authority, the specific requirements for analytical methods can be specified in the control mechanism issued to the indirect discharger.

EPA received several comments that indicated that while the commenters supported the concept established in the proposed rule, they believed additional flexibility should be provided to account for instream dilution. Specifically, the commenters requested that the criteria defining sufficiently sensitive be revised such that the minimum level would be compared to either ''the applicable water quality criterion, wasteload allocation, permit limit, or other critical regulatory value.'' EPA believes that the final rule need only require comparison of a method's minimum level with the applicable water quality criterion, as proposed, and that this language is sufficiently flexible to address the commenters' concern. Under this language, the permitting authority has adequate discretion to determine whether the data provided with a permit application were collected with methods that are sufficiently sensitive to measure at the relevant regulatory value. For example, where a permitting authority has conducted a timely and relevant dilution analysis (including an evaluation of ambient pollutant concentrations) and documented this analysis in the permit record, the permitting authority could provide this information to the applicant prior to the applicant sampling for the permit application. The applicant would then only need to show that the method it has selected has a minimum level that is at least as sensitive as necessary to determine compliance with the water quality criterion, after accounting for allowable dilution. The water quality criterion as adjusted for allowable dilution would be the ''applicable water quality criterion'' in this case, and the method would be ''sufficiently sensitive'' if it measures at this level. EPA considers this approach consistent with the requirements established in today's rule. For these reasons, EPA is not revising the regulatory text to incorporate the language suggested by the commenters.

C. Burden

EPA received a few comments indicating that site-specific situations might increase the implementation costs of the rule beyond those costs outlined in the proposed rule. Some of these commenters provided examples of when site-specific conditions might result in increased costs. EPA recognizes that the burden estimated is a national average and that the cost for an individual facility could be higher or lower than that average. However, EPA does not believe that the information provided by the commenters is representative of the impact for a typical facility affected by this rule, nor does it alter the Agency's original burden estimates.

EPA also recognizes that in some cases, use of a more sensitive method could have the practical effect of requiring a facility to adopt additional pollution control measures, even if the permit limit remained unchanged. This is because a more sensitive method may detect the presence of a pollutant that was previously undetected. EPA emphasizes that this rule would not be responsible for any change in stringency of the permit requirements in such a case, but acknowledges that a facility may incur additional pollution control costs if a previously undetected pollutant is later detected by the use of a sufficiently sensitive method, and additional treatment is required to meet the existing permit limit. In general, when EPA develops a cost analysis for a new regulation, there is an assumption made of full compliance with existing requirements. EPA does not have data that would allow it to predict in advance where or how often this situation might occur, or what a facility would be required to do to address it. Therefore, EPA has not attempted to quantify any such costs, as they are outside the scope of this rulemaking.

As noted above, where a technology-based requirement is specified as ''zero discharge'' or ''no detect,'' the permitting authority may take into account the sensitivity of the method used to establish the requirement when determining if a method is ''sufficiently sensitive.'' EPA recognizes that if a more sensitive method is approved after such a requirement has been established, its use may be inconsistent with the technological basis of the original requirement. In situations where a technology-based requirement reflects a technology that eliminates the discharge of the subject pollutant altogether, the Agency included costs that reflect that technology, the newer sensitive method is appropriate, and the permittee would not incur additional costs. However, where a technology-based limit reflects a technology that may not achieve the minimum level of the newer more sensitive method, the Director may determine that the method on which the requirement was originally based is ''sufficiently sensitive'' to determine compliance, as understood at the time the requirement was established, and there would thus be no additional control costs incurred by the facility.

EPA received a few comments regarding compliance with requirements under the statutory and Executive Order reviews contained in the proposed rule. EPA believes that there was a misunderstanding on the part of the commenters regarding the intent of the rule that led the commenters to believe that the rule would result in a higher cost of implementation than that estimated by EPA. EPA believes that the Agency has met its responsibilities under the applicable statutory and Executive Orders.

IV. The Final Rule

The final rule adds a new 40 CFR 122.21(e)(3) and revises 122.44(i)(1)(iv) to require that where EPA-approved methods exist, NPDES applicants use sufficiently sensitive EPA-approved analytical methods when submitting information quantifying the presence of pollutants in a discharge and that the Director must prescribe that only sufficiently sensitive EPA-approved analytical test methods be used for analyses of pollutants or pollutant parameters under the permit. EPA is also providing a cross-reference to these changes in a new 40 CFR 136.1(c). For the purposes of this rulemaking, if monitoring requirements are included as a condition of a general permit, those requirements are subject to the provisions established in 122.44(i)(1)(iv). Only these specific parts of the regulations undergoing revision are subject to challenge under section 509(b) of the Clean Water Act.

In addition, based on public comments, EPA made certain minor modifications to the final rule from the original proposal. Specifically, EPA amended 122.21(e)(3)(i)(B) and 122.44(i)(1)(iv)(A)(1) to add the word ''or'' when defining the term ''sufficiently sensitive,'' which was unintentionally omitted in the proposed rule. In addition, EPA added ''pollutant or pollutant parameter'' to 122.21(e)(3)(i)(C) and 122.44(i)(1)(iv)(A) to clarify the applicability of the criteria established under the sufficiently sensitive method definition. EPA also removed the second ''in accordance with'' in the introductory paragraphs for 122.21(e)(3) and 122.44(i)(1)(iv) to clarify that the method selected must be approved under 40 CFR part 136 *or* required under 40 CFR chapter I, subchapter N or O.

EPA removed language in 122.44(i)(1)(iv)(A)(2) of the proposed rule because it was not applicable to requirements established in this section and created confusion about the implementation of the rule. In this instance, even if the permittee believes

they are discharging above the permit limit and could potentially use a less sensitive method, the permitting authority is responsible for prescribing an EPA-approved method, where available, that is sensitive enough to detect at or below the permit limit in order to properly assess compliance with the permit.

EPA revised the proposed regulatory text at 122.21(e)(3)(ii) and 122.41(i)(1)(iv)(B) for instances where there are no EPA-approved methods. The proposed language included additional requirements for situations where there are no EPA-approved methods. Specifically, the proposed rule would have required that applicants and permitting authorities select a ''sufficiently sensitive'' non EPA-approved method and that applicants provide a description of the method, including the minimum level. The situation in which there are no EPA-approved methods is uncommon because there are EPA-approved methods for most pollutants or pollutant parameters screened and regulated under the NPDES program. In addition, the existing regulations already require that applicants select a suitable method and provide a description of the method. Based on public comments, EPA determined that this additional requirement was unnecessary and has revised the regulatory text to revert the existing language in 40 CFR 122.21 and 122.41. As a result, today's rule does not specify that non-EPA-approved methods must be sufficiently sensitive. To clarify this point, EPA also added language to the introduction of 122.21(e)(3) to specify that the requirement to use a sufficiently sensitive method applies ''except as specified in 122.21(e)(3)(ii).''

EPA amended 122.21(e)(3)(ii) by adding regulatory text to clarify that in the case where there are no EPA-approved methods, applicants may consider other relevant factors when selecting an appropriate method. In addition, EPA revised the proposed regulatory text to change ''or otherwise required by the Director'' to ''and not otherwise required by the Director'' to clarify that this provision applies to a situation where no EPA-approved methods exist *and* the Director has not required the use of a specific non-EPA-approved method. In this situation, the permit applicant may select a suitable non-EPA-approved method and provide a description of the method.

Finally, in both places where the new definition of ''sufficiently sensitive'' appears, EPA added a note to clarify that, consistent with 40 CFR part 136, permittees have the option of providing matrix or sample-specific minimum levels rather than the published levels. In addition, the note clarifies that where a permittee can demonstrate that, despite a good faith effort to use a method that would otherwise meet the definition of ''sufficiently sensitive,'' the analytical results are not consistent with the QA/QC specifications for that method, then the Director may determine that the method is not performing adequately and a different method should be selected from the remaining EPA-approved methods consistent with 40 CFR 122.21(e)(3)(i) and 40 CFR 122.44(i)(1)(iv)(A). Where no other EPA-approved methods exist, a method should be selected consistent with 40 CFR 122.21(e)(3)(ii) and 40 CFR 122.44(i)(1)(iv)(B).

V. Impacts

Entities that discharge to waters of the United States vary in terms of the quantity of their discharges, the potential constituents contained in their discharges, and their operation and maintenance practices. Consequently, the Director's NPDES application requirements vary depending on applicant type. For example, Form 2A for municipalities requires minimal screening for POTWs with design flows under 100,000 gallons per day; however, for POTWs with design flows above 1 million gallons per day, multiple priority pollutant scans are required. Similarly, existing industrial and commercial facilities that complete Form 2C are required to test for toxic pollutants based on the nature of their manufacturing operation. To assist permitting authorities (EPA regions, States, and Tribes), EPA developed several NPDES permit application forms. Table IV–1 provides a list of these forms and the discharger type(s) for which they are intended. Permitting authorities may use EPA's forms or comparable forms of their own.

TABLE IV–1—EPA NPDES PERMIT APPLICATION FORMS BY APPLICANT TYPE

	Form or request	Applicant type
1	Form 1	New and existing applicants, except POTWs and treatment works treating domestic sewage.
2	Form 2A	New and existing POTWs (i.e., municipal facilities).
3	Form 2B	New and existing concentrated animal feeding operations (CAFOs) and aquatic animal production facilities.
4	Form 2C	Existing industries discharging process wastewater.
5	Form 2D	New industries discharging process wastewater.
6	Form 2E	New and existing industries discharging non-process wastewater only.
7	Form 2F	New and existing industries discharging stormwater.
8	40 CFR 122.21(r) and 122.22(d)	New and existing industries with cooling water intake structures.
9	Form 2S	New and existing POTWs and other treatment works treating domestic sewage (covers sludge).

As noted earlier, permitting authorities issue and develop effluent limitations for individual NPDES permits after analyzing the data contained in each permittee's application. The NPDES permit prescribes the conditions under which the facility is allowed to discharge to ensure the facility's compliance with the CWA's technology-based and water quality-based requirements. NPDES permits typically include restrictions on the quantity of pollutants that a permittee may discharge and require the permittee to conduct routine measurements of, and report on, a number of parameters using EPA-approved, pollutant-specific test procedures (or approved alternative test procedures).

In 2012 EPA submitted an Information Collection Request (ICR) to the Office of Management and Budget (OMB) that, in part, updated the Agency's burden estimates for applicants to complete Forms 1, 2A, 2C–2F, and 2S and for permitting authorities to review and process such forms.[10] The renewal ICR did not include updated estimates for Form 2B or for forms associated with cooling water intake structures (Item 8 in Table IV–1). Updated estimates to complete

[10] USEPA. ''Information Collection Request (ICR) for National Pollutant Discharge Elimination System (NPDES) Program (Renewal),'' OMB Control No. 2040–0004, EPA ICR No. 0229.20, March 2012.

those forms were contained in separate ICRs.[11] The existing ICRs include annual burden estimates for completing NPDES permit applications and for conducting ongoing compliance monitoring for both new and existing NPDES permittees. EPA's expectation is that permit applicants and permittees will use a range of methods based on a need to appropriately quantify pollutants in their discharge. To calculate cost and burden, the ICRs use an average cost for analytical methods, which is then translated into burden hours.

To assess the impact of this final rule, EPA also assessed the cost information for 40 CFR Part 136 methods found in the National Environmental Methods Index (NEMI) at *http://www.nemi.gov.* The NEMI site describes the ''relative cost'' as the cost per procedure of a typical analytical measurement using the specified methods (i.e., the cost of analyzing a single sample). Additional considerations affect total project costs (e.g., labor and equipment/supplies for a typical sample preparation, quality assurance/quality control requirements to validate results reported, number of samples being analyzed). EPA's review of the cost ranges provided in NEMI indicated that there was generally little difference in the cost ranges across the EPA-approved analytical methods for a particular pollutant. A table with the NEMI cost ranges is included in the record. While EPA acknowledges that there are cost differentials for some facilities based on case-specific situations, on the basis of the analytical cost ranges provided in NEMI, and the assumptions used in the current ICRs (i.e., that applicants and permittees will use a range of available approved methods), the final rule is expected to result in little or no new or increased analytical burden to applicants or permittees.

The existing ICRs also account for the ongoing burden to permitting authorities to review applications and to issue NPDES permits annually. They also account for the ongoing burden associated with reviewing discharge monitoring and other reports for compliance assessment purposes. Finally, the existing ICRs account for program revisions where they are necessary because the controlling Federal statutes or regulations were modified.

As noted above, EPA also recognizes that in some cases, use of a more sensitive method could have the practical effect of requiring a facility to adopt additional pollution control measures, even if the permit limit remained unchanged. EPA does not have data that would allow it to predict in advance where or how often this situation might occur, or what a facility would be required to do to address it. EPA has not attempted to quantify the costs of any such new control measures that might be adopted, as they are outside the scope of this rulemaking.

VI. Compliance Dates

Following issuance of this rule, authorized states have up to one year to revise, as necessary, their NPDES regulations to adopt the requirements of this rule, or two years if statutory changes are needed, as provided at 40 CFR 123.62.

VII. Statutory and Executive Order Reviews

A. Executive Order 12866: Regulatory Planning and Review and Executive Order 13563: Improving Regulation and Regulatory Review

Under Executive Order 12866 (58 FR 51735, October 4, 1993), this action is a ''significant regulatory action.'' Accordingly, EPA submitted this action to the Office of Management and Budget (OMB) for review under Executive Orders 12866 and 13563 (76 FR 3821, January 21, 2011) and any changes made in response to OMB recommendations have been documented in the docket for this action.

B. Paperwork Reduction Act

This action does not impose any new information collection burden. The final rulemaking requires the use of sufficiently sensitive EPA-approved analytical test methods, where they exist, when applying for an NPDES permit and when performing sampling and analysis pursuant to monitoring requirements in an NPDES permit. However, it does not change the recordkeeping or reporting requirements associated with the use of analytical methods. The Office of Management and Budget (OMB) has previously approved the information collection requirements contained in the existing regulations (which cover all potential NPDES applicants) under the provisions of the Paperwork Reduction Act, 44 U.S.C. 3501 et seq. and has assigned OMB control numbers, as summarized in section V (Impacts) of this preamble. The OMB control numbers for EPA's regulations in 40 CFR are listed in 40 CFR part 9.

C. Regulatory Flexibility Act

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

For purposes of assessing the impacts of this final rule on small entities, ''small entity'' is defined as (1) a small business based on the Small Business Administration regulations at 13 CFR 121.201; (2) a small governmental jurisdiction that is a government of a city, county, town, school district, or special district with a population of less than 50,000; or (3) a small organization that is any not-for-profit enterprise which is independently owned and operated and is not dominant in its field.

After considering the economic impacts of this final rule on small entities, I certify that this action will not have a significant economic impact on a substantial number of small entities. EPA has determined that the incremental analytical costs that NPDES permit applicants and permittees may bear as a result of this rule are minimal and would not rise to the level of a significant economic impact on a substantial number of small entities.

D. Unfunded Mandates Reform Act

This rule does not contain a Federal mandate that might 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. Thus, this final rule is not subject to the requirements of sections 202 and 205 of the UMRA. EPA has further determined that this rule contains no regulatory requirements that might significantly or uniquely affect small governments. Thus, this final rule is not subject to the requirements of section 203 of UMRA.

[11] USEPA. ''Supporting Statement for the Information Collection Request for the NPDES Regulation and Effluent Limitation Guidelines and Standards for Concentrated Animal Feeding Operations,'' OMB Control No. 2040–0250, EPA ICR No. 1989.09, January 2014.

USEPA, ''Information Collection Request (ICR) for Cooling Water Intake Structures at Phase III Facilities (Final Rule),'' OMB Control No. 2040–0268, EPA ICR No. 2169.05, January 2014.

USEPA, ''Information Collection Request (ICR) for Cooling Water Intake Structures Phase II Existing Facilities (Renewal),'' OMB Control No. 2040–0257, EPA ICR No. 2060.06, January 2014.

USEPA, ''Information Collection Request (ICR) for Cooling Water Intake Structures New Facility Rule (Renewal),'' OMB Control No. 2040–0241, EPA ICR No. 1973.05, December 2011.

E. Executive Order 13132: Federalism

This final rule does not have federalism implications. When promulgated, it will not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of governments, as specified in Executive Order 13132 (64 FR 43255, August 10, 1999). This final rule does not change the relationship between the national government and the States or change their roles and responsibilities. Rather, this final rulemaking requires that sufficiently sensitive EPA-approved analytical test methods be used, where they exist, when applying for an NPDES permit and when performing sampling and analysis pursuant to monitoring requirements in an NPDES permit. EPA does not expect this final rule to have any impact on local governments.

Furthermore, the revised regulations would not alter the basic state-federal scheme established in the CWA, under which EPA authorizes states to carry out the NPDES permitting program. EPA expects the revised regulations to have little effect on the relationship between, or the distribution of power and responsibilities among, the Federal and State governments.

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

This final rule does not have tribal implications, as specified in Executive Order 13175, ''Consultation and Coordination with Indian Tribal Governments'' (65 FR 67249, November 9, 2000). It will not have substantial direct effects on tribal governments, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes, as specified in Executive Order 13175. The final rule requires that sufficiently sensitive EPA-approved analytical test methods must be used, where they exist, when applying for an NPDES permit and when performing sampling and analysis pursuant to monitoring requirements in an NPDES permit. Nothing in this final rule would prevent an Indian tribe from exercising its own organic authority to deal with such matters.

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

The final rule is not subject to Executive Order 13045, ''Protection of Children from Environmental Health Risks and Safety Risks'' (62 FR 19885, April 23, 1997), because it is not economically significant and the Agency does not believe that the environmental health and safety risks addressed by this action present a disproportionate risk to children.

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

This rulemaking is not subject to Executive Order 13211, ''Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use'' (66 FR 28355, May 22, 2001), because it is not likely to have a significant adverse effect on the supply, distribution, or use of energy.

I. National Technology Transfer and Advancement Act

Section 12(d) of the National Technology Transfer and Advancement Act (NTTAA) of 1995 (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, and business practices) that are developed or adopted by voluntary consensus standard bodies. The NTTAA directs EPA to provide explanations to Congress, through OMB, when the Agency decides not to use available and applicable voluntary consensus standards. This final rulemaking does not change agency policy or requirements with respect to the use of voluntary consensus standards for the analysis of pollutants by NPDES permit applicants or permittees.

J. Executive Order 12898 (Federal Actions To Address Environmental Justice in Minority Populations and Low-Income Populations)

Executive Order 12898 (59 FR 7629, February 16, 1994) establishes federal executive policy on environmental justice. Its main provision directs federal agencies, to the greatest extent practicable and permitted by law, to make environmental justice part of their mission by identifying and addressing, as appropriate, disproportionately high and adverse human health or environmental effects of their programs, policies, and activities on minority populations and low-income populations in the United States.

EPA has determined that this final rule will not have disproportionately high and adverse human health or environmental effects on minority or low-income populations because it does not affect the level of protection provided to human health or the environment. As explained above, the Agency does not have reason to believe that the rule addresses environmental health and safety risks that present a disproportionate risk to minority populations and low-income populations.

K. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 et seq., as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. A major rule cannot take effect until 60 days after it is published in the **Federal Register**. This action is not a ''major rule'' as defined by 5 U.S.C. 804(2). This rule will be effective September 18, 2014.

List of Subjects

40 CFR Part 122

Administrative practice and procedure, Confidential business information, Environmental protection, Hazardous substances, Reporting and recordkeeping requirements, Water pollution control.

40 CFR Part 136

Environmental protection, Incorporation by reference, Reporting and recordkeeping requirements, Water pollution control.

Dated: August 6, 2014.

Gina McCarthy,

Administrator.

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

PART 122—EPA ADMINISTERED PERMIT PROGRAMS: THE NATIONAL POLLUTANT DISCHARGE ELIMINATION SYSTEM

■ 1. The authority citation for part 122 continues to read as follows:

Authority: The Clean Water Act, 33 U.S.C. 1251 *et seq.*

■ 2. Section 122.21, is amended by adding a new paragraph (e)(3), to read as follows:

§ 122.21 Application for a permit (applicable to State programs, see § 123.25).

* * * * *

(e) * * *

(3) Except as specified in 122.21(e)(3)(ii), a permit application shall not be considered complete unless all required quantitative data are collected in accordance with sufficiently sensitive analytical methods approved under 40 CFR part 136 or required under 40 CFR chapter I, subchapter N or O.

(i) For the purposes of this requirement, a method approved under 40 CFR part 136 or required under 40 CFR chapter I, subchapter N or O is ''sufficiently sensitive'' when:

(A) The method minimum level (ML) is at or below the level of the applicable water quality criterion for the measured pollutant or pollutant parameter; or

(B) The method ML is above the applicable water quality criterion, but the amount of the pollutant or pollutant parameter in a facility's discharge is high enough that the method detects and quantifies the level of the pollutant or pollutant parameter in the discharge; or

(C) The method has the lowest ML of the analytical methods approved under 40 CFR part 136 or required under 40 CFR chapter I, subchapter N or O for the measured pollutant or pollutant parameter.

Note to paragraph (e)(3)(i)(C): Consistent with 40 CFR part 136, applicants have the option of providing matrix or sample specific minimum levels rather than the published levels. Further, where an applicant can demonstrate that, despite a good faith effort to use a method that would otherwise meet the definition of ''sufficiently sensitive'', the analytical results are not consistent with the QA/QC specifications for that method, then the Director may determine that the method is not performing adequately and the applicant should select a different method from the remaining EPA-approved methods that is sufficiently sensitive consistent with 40 CFR 122.21(e)(3)(i). Where no other EPA-approved methods exist, the applicant should select a method consistent with 40 CFR 122.21(e)(3)(ii).

(ii) When there is no analytical method that has been approved under 40 CFR part 136, required under 40 CFR chapter I, subchapter N or O, and is not otherwise required by the Director, the applicant may use any suitable method but shall provide a description of the method. When selecting a suitable method, other factors such as a method's precision, accuracy, or resolution, may be considered when assessing the performance of the method.

* * * * *

■ 3. Section 122.44 is amended by revising paragraph (i) (1) (iv) to read as follows:

§ 122.44 Establishing limitations, standards, and other permit conditions (applicable to State NPDES programs, see § 123.25).

* * * * *

(i) * * *

(1) * * *

(iv) According to sufficiently sensitive test procedures (i.e., methods) approved under 40 CFR part 136 for the analysis of pollutants or pollutant parameters or required under 40 CFR chapter I, subchapter N or O.

(A) For the purposes of this paragraph, a method is ''sufficiently sensitive'' when:

(*1*) The method minimum level (ML) is at or below the level of the effluent limit established in the permit for the measured pollutant or pollutant parameter; or

(*2*) The method has the lowest ML of the analytical methods approved under 40 CFR part 136 or required under 40 CFR chapter I, subchapter N or O for the measured pollutant or pollutant parameter.

Note to paragraph (i)(1)(iv)(A)(*2*): Consistent with 40 CFR part 136, applicants or permittees have the option of providing matrix or sample specific minimum levels rather than the published levels. Further, where an applicant or permittee can demonstrate that, despite a good faith effort to use a method that would otherwise meet the definition of ''sufficiently sensitive'', the analytical results are not consistent with the QA/QC specifications for that method, then the Director may determine that the method is not performing adequately and the Director should select a different method from the remaining EPA-approved methods that is sufficiently sensitive consistent with 40 CFR 122.44(i)(1)(iv)(A). Where no other EPA-approved methods exist, the Director should select a method consistent with 40 CFR 122.44(i)(1)(iv)(B).

(B) In the case of pollutants or pollutant parameters for which there are no approved methods under 40 CFR part 136 or methods are not otherwise required under 40 CFR chapter I, subchapter N or O, monitoring shall be conducted according to a test procedure specified in the permit for such pollutants or pollutant parameters.

* * * * *

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

■ 4. The authority citation for part 136 continues to read as follows:

Authority: Secs. 301, 304(h), 307, and 501(a) Pub. L. 95–217, 91 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.)

■ 5. Section 136.1 is amended by adding a new paragraph (c) to read as follows:

§ 136.1 Applicability.

* * * * *

(c) For the purposes of the NPDES program, when more than one test procedure is approved under this part for the analysis of a pollutant or pollutant parameter, the test procedure must be sufficiently sensitive as defined at 40 CFR 122.21(e)(3) and 122.44(i)(1)(iv).

[FR Doc. 2014–19265 Filed 8–18–14; 8:45 am]

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DEPARTMENT OF THE INTERIOR

Office of the Secretary

43 CFR Part 2

[145D0102DM DLSN00000.000000 DS62400000 DX62401]

RIN 1090–AA94

Privacy Act Regulations; Exemption for the Debarment and Suspension Program

AGENCY: Office of the Secretary, Interior.

ACTION: Final rule.

SUMMARY: The Department of the Interior is issuing a final rule to amend its regulations to exempt certain records of the Debarment and Suspension Program system of records from particular provisions of the Privacy Act because these records contain investigatory material.

DATES: This final rule is effective September 18, 2014.

FOR FURTHER INFORMATION CONTACT: Teri Barnett, Departmental Privacy Officer, U.S. Department of the Interior, 1849 C Street NW., Mail Stop 5547 MIB, Washington, DC 20240. Email at *privacy@ios.doi.gov.*

SUPPLEMENTARY INFORMATION:

Background

The Department of the Interior (DOI) published a notice of proposed rulemaking in the **Federal Register**, 76 FR 52295, August 22, 2011, proposing to