Executive Order 12866—Regulatory Planning and Review

Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). The Executive Order classifies a “significant regulatory action,” requiring review by the Office of Management and Budget (OMB) unless OMB waives such review, as any regulatory action that is likely to result in a rule that may: (1) Have an annual effect on the economy of $100 million or more or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities; (2) create a serious inconsistency or otherwise interfere with an action taken or planned by another agency; (3) materially alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raise novel legal or policy issues arising out of legal mandates, the President’s priorities, or the principles set forth in the Executive Order.

The economic, interagency, budgetary, legal, and policy implications of this proposed rule have not been examined, and it has been determined not to be a significant regulatory action under Executive Order 12866 because it is unlikely to result in a rule that may raise novel legal or policy issues arising out of legal mandates, the President’s priorities, or the principles set forth in the Executive Order.

Unfunded Mandates

The Unfunded Mandates Reform Act of 1995 requires, at 2 U.S.C. 1532, that agencies prepare an assessment of anticipated costs and benefits before issuing any rule that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100 million or more (adjusted annually for inflation) in any 1 year. This proposed rule would have no such effect on State, local, and tribal governments, or on the private sector.

Catalog of Federal Domestic Assistance Numbers and Titles

The Catalog of Federal Domestic Assistance program numbers and titles for this proposal are 64.104, Pension for Non-Service-Connected Disability for Veterans, and 64.109, Veterans Compensation for Service-Connected Disability.

Signing Authority

The Secretary of Veterans Affairs, or designee, approved this document and authorized the undersigned to sign and submit the document to the Office of the Federal Register for publication electronically as an official document of the Department of Veterans Affairs.

Bill R. Gingrich, Chief of Staff, Department of Veterans Affairs, approved this document on June 17, 2010 for publication.

List of Subjects in 38 CFR Part 4

Disability benefits, Pensions, Veterans.

Dated: June 18, 2010.

William F. Russo,
Director of Regulations Management, Office of the General Counsel.

For the reasons set out in the preamble, 38 CFR part 4, subpart B, is proposed to be amended as set forth below:

PART 4—SCHEDULE FOR RATING DISABILITIES

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

Authority: 38 U.S.C. 1155, unless otherwise noted.

Subpart B—Disability Ratings

2. In § 4.124a, revise diagnostic code 8017 to read as follows:

§4.124a Schedule of ratings—neurological conditions and convulsive disorders.

* * * * * 8017 Amyotrophic lateral sclerosis .................................................. 100

Note: Consider the need for special monthly compensation.

* * * * *

[FR Doc. 2010–15169 Filed 6–22–10; 8:45 am]
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 permits after analyzing the information contained in the application or in the case of a general permit, the information submitted to demonstrate eligibility for coverage. The NPDES permit prescribes the conditions under which the facility is allowed to discharge pollutants and that will ensure the facilities’ 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 and require the permittee to 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, pollutant-specific test procedures (or approved alternative test procedures) when measuring the pollutants in their discharges.

The purpose of today’s proposal is to clarify that NPDES applicants and permittees must use sufficiently sensitive analytical methods when quantifying the presence of pollutants in a discharge, and the Director 2 must require and accept only such data. The broad universe of entities 3 that would be affected by this proposal includes NPDES permitting authorities and municipal and industrial applicants and permittees (Table I–1). The impact of this proposal, 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.

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.

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1 Where the term “pollutant” is used, it refers to both pollutants and pollutant parameters.
2 The term “Director” refers to the permitting authority. Per 40 CFR 122.2, “Director” means the Regional Administrator or the State Director, as the context requires, or an authorized representative. When there is no “approved State program” and there is an EPA-administered program, “Director” means the Regional Administrator. When there is an approved State program, “Director” normally means the State Director. In some circumstances, however, EPA retains the authority to take certain actions even when there is an approved State program. (For example, when EPA has issued an NPDES permit prior to the approval of a State program, EPA may retain jurisdiction over that permit after program approval, see 40 CFR 123.1.) In such cases, the term “Director” means the Regional Administrator and not the State Director.
3 Although terms such as “authorities,” “applicants,” and “permittees” imply individuals, EPA uses these terms to refer to entities.
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 would promulgate the rule being proposed today 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 501(a) of the CWA authorizes the Administrator of EPA to prescribe such regulations as are necessary to carry out the act. Section 301(a) of the CWA prohibits the discharge of any pollutant into navigable waters unless the discharge complies 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 of performance 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 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)(ii)]. If the Director determines that a discharge causes, or has the reasonable potential to cause or contribute 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(b) 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 401 of 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 136, although some requirements are codified in other parts (e.g., 40 CFR chapter 1, subchapters N and O).

The Director is authorized under 40 CFR 122.21(e) to determine when an NPDES permit application is complete. Moreover, the Director shall not begin processing a 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. Under 40 CFR 122.28(b)(2), dischargers (or treatment works treating domestic sewage) seeking coverage under a general permit must submit to the Director a written NOI to be covered by the general permit (with some exceptions set forth elsewhere in 40 CFR 122.28(b)(2)). The contents of the NOI must be specified in the general permit, and they must require the submission of information necessary for adequate program implementation. Finally, 40 CFR 122.41(j)(1) requires NPDES permits to specify that sampling and measurements taken for the purposes 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 for inspection, monitoring, and issuing permits that are applicable to at least the same extent as those under section 308.

As summarized above, the legal requirements and authorities exist for EPA to require NPDES applicants and permittees to use sufficiently sensitive 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 approved multiple methods for CWA pollutants under 40 CFR 136 and 40 CFR chapter I, subchapters N and O. Some of the approved analytical test methods have greater sensitivities and lower minimum levels or more methods.

The term “minimum level” refers to either the lowest calibration point in a method or a multiple of the method detection limit (MDL), whichever is higher. Minimum levels may be obtained in several ways: They may be published in a method; they may be the lowest acceptable calibration point used.
detection limits (MDLs)\(^6\) than other approved methods for the same pollutant. This situation often occurs because of advances having been 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.

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 with precision and accuracy so that they will be meaningful to the decision-making process. Among other things, data must be provided at a level 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 aim 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.\(^7\)

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](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 clarified to ensure that applicants and permittees use sufficiently sensitive analytical methods for all pollutants, not just mercury. EPA is proposing to incorporate language in the regulations that extends the requirement to use sufficiently sensitive test methods to all pollutants. EPA is also proposing to codify the definition of “sufficiently sensitive” to include an additional criterion that was not part of the 2007 memorandum, as described below.

### III. Scope and Rationale of the Proposed Rule

This proposed rule clarifies that NPDES applicants and permittees must use sufficiently sensitive analytical test methods when submitting information characterizing the discharge in an NPDES permit application and when performing sampling and analysis pursuant to monitoring requirements in an NPDES permit. In addition, the proposed rule clarifies that the Director must require NPDES applicants and permittees to use sufficiently sensitive analytical test methods and accept only data analyzed by such methods. EPA proposes adding or modifying language to define “sufficiently sensitive” at 40 CFR 122.21(e)(3) and 122.44(i)(1)(iv). EPA also proposes providing a cross-reference to these changes at 40 CFR 136.1(c). For the purposes of this rulemaking, if monitoring requirements are included as a condition of the general permit, these requirements would be subject to the provisions established in 122.44(i)(1)(iv).

As discussed earlier, it is critical that the Director make permitting decisions based on accurate data and, thus, sound science. The use of imprecise analytical methods could lead the Director to make assumptions regarding the presence or absence of a pollutant in an applicant’s discharge. These assumptions, in turn, could result in the Director’s making an incorrect permitting decision (e.g., the decision not to include a limit in a permit when, in fact, a waste stream concentration of a pollutant will cause, have the reasonable potential to cause, or contribute to an excursion above an applicable water quality criterion). Moreover, if the Director were to include imprecise analytical methods in permits for compliance monitoring purposes, the use of such methods could result in undetected exceedances of permit limits.

Although EPA has approved multiple analytical methods for individual pollutants under 40 CFR 136, the Agency has historically expected that applicants and permittees 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. This proposed rule, therefore, would clarify that NPDES applicants and permittees must use sufficiently sensitive analytical methods when quantifying the presence of pollutants in a discharge and that the Director must require and accept only such data.

EPA proposes defining the term “sufficiently sensitive” in two sections of the Federal NPDES regulations—at 40 CFR 122.21(e) (Permit Application Completeness) as a new subsection (3) and at 40 CFR 122.44(i)(1)(iv) (Monitoring Requirements). EPA also proposes modifying 40 CFR 136.1 (Applicability) by adding a new
acknowledges that a laboratory might achieve MDLs and minimum levels lower than those published when the promulgated method was developed. Thus, the Director should not rely solely on MDLs or minimum levels in published methods because they give only an upper, not a lower, bound on the lab’s MDL and minimum level. Flexibility is provided at 40 CFR 136.6, which allows a laboratory to demonstrate performance better than the MDL or minimum level published in a method.

The final provision is intended to address situations where no approved analytical method exists under part 136, is required under subchapter N or O, or is otherwise required by the Director. In such situations, an applicant may use any suitable sufficiently sensitive method but shall provide a description of the method that includes documentation of the minimum level. Where an EPA-approved analytical method is nonexistent under part 136 or is not required under subchapter N or O for a pollutant limited in an NPDES permit, the Director must specify a sufficiently sensitive analytical method as a condition of the NPDES permit, consistent with the criteria established in this proposed rulemaking at 40 CFR 122.44(j)(1)(iv)(A)–(B).

Under the CWA, authorized NPDES States, Territories, and Indian Tribes must have in place legal authorities that are at least as stringent as the requirements in certain parts of the EPA regulations. See 40 CFR 123.25. The requirements of sections 122.21(e) and 122.44(i), which are the subject of this proposal, are among those that States must include within their own programs. Therefore, once the revised regulations that EPA is proposing today are finalized, States will need to amend their own legal authorities, where necessary, to ensure that only sufficiently sensitive methods are used to produce data for permit applications and for monitoring under a permit. See 40 CFR 123.62(e).

In some cases, States currently have State statutes or regulations that require

NPDES applicants to use a specific analytical method or achieve a specific minimum level for a particular pollutant (or they have a State policy or guidance that recommends a specific method or minimum level). A problem would arise if the State currently requires a particular method or minimum level that is not “sufficiently sensitive” as defined in new EPA regulations. In these situations, EPA would expect States to revise their statutes or regulations so that if they require the use of a particular method or minimum level, it is one that is sufficiently sensitive. States would need to revise any policy guidelines as well. (No problem would arise, however, if the method or minimum level currently required by the State does qualify as “sufficiently sensitive.”) EPA will provide regular updates on its Web site at http://www.epa.gov/waterscience/methods to keep permitting authorities and permittees informed of method updates and revised water quality criteria to better enable the permitting authorities to determine that their requirements for applicants and permittees remain sufficiently sensitive.

The following example is provided to help clarify the importance of using sufficiently sensitive test methods in the NPDES program:

Example III–1—Mercury

Measurements included with an NPDES permit application and with reports required to be submitted under the NPDES permit must generally be made using analytical methods approved by EPA under 40 CFR 136. (See 40 CFR 136.1, 136.4, 136.5, 122.21(g)(7), and 122.41(i).) EPA has four approved methods for mercury under 40 CFR 136—EPA Methods 245.1, 245.2, 1631E, and 245.7. The first two methods, approved by EPA in 1974, can achieve measurement of mercury down to 200 parts per trillion (ppt). EPA approved Method 1631 Revision E in 2002. Method 1631E has a minimum level of 0.5 ppt, making it 400 times more sensitive than EPA Methods 245.1 and 245.2. In fact, the sensitivity of Methods 245.1 and 245.2 when last updated in 1994 and 1979, respectively, was well above the water quality criteria now adopted in most States as well as the criteria included by EPA in its final “Water Quality Guidance for the Great Lakes System” for the protection of aquatic life and human health, which generally fall in the range of 1 to 50 ppt. In contrast, Method 1631E, with

*This provision is adopted from existing language in 40 CFR 122.21(g)(7).


Many States have adopted mercury water quality criteria of 12 parts per trillion (ppt) for the protection of aquatic life and 50 ppt for the
a minimum level of 0.5 ppt, supports the measurement of mercury at these low levels.

On March 12, 2007, EPA published the Methods Update Rule, or MUR (72 FR 11200), under which the Agency approved Method 245.7 for mercury and also modified versions of other EPA-approved methods for the parameter. This method change applies to the implementation of both water column criteria and fish tissue criteria in permits. Method 245.7 has a minimum level of 5.0 ppt, making it 40 times more sensitive than Methods 245.1 and 245.2. Methods 245.1 and 245.2 may be modified to achieve lower minimum levels. Modifications to an EPA-approved method for mercury that meet the method performance requirements of 40 CFR 136.6 are considered to be approved methods and require no further EPA approval. (See 72 FR 11239–40, March 12, 2007.) For analytical method modifications that do not fall within the flexibility of 40 CFR 136.6, the modified methods may be approved under the alternate test procedure program, as defined at 40 CFR 136.4 and 136.5.

As noted, most States have adopted water quality criteria for the protection of aquatic life and human health that fall in the range of 1 to 50 ppt. If an applicant or permittee used Methods 245.1 and 245.2, “the absence of a quantitative result” would show only that mercury levels are below 200 ppt (based on a minimum level of 200 ppt) but would not establish that the discharge is at or below the applicable water quality criterion. In such a circumstance, a permit writer would possibly lack the information needed to make a reasonable potential determination. Use of an insufficiently sensitive method when performing routine monitoring under an NPDES permit could also yield data that would not be adequate for the Director to assess compliance. In contrast, if the applicant used Method 1631E (or 245.7), which can detect and quantify mercury concentrations at or below the low water quality criteria levels, the permit writer would have adequate information to make a reasonable potential determination. Therefore, EPA proposes to clarify in the regulations that the Director must consider an NPDES permit application incomplete until the applicant submits analytical data using a sufficiently sensitive method as that term is defined in this rulemaking, and when specifying in a permit which analytical methods the permittee may use, the Director may only specify sufficiently sensitive methods.

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

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 such as the use of reagents similar in properties to ones used in the approved method, changes in the equipment operating parameters such as the use of an alternate more sensitive wavelength, adjusting the sample volume to optimize method performance, and changes in the calibration ranges (provided that the modified range covers any relevant regulatory limit).

TABLE IV—EPA NPDES PERMIT APPLICATION FORMS BY APPLICANT TYPE

[Table IV—EPA NPDES Permit Application Forms by Applicant Type]

[Form or request: New and existing applicants, except POTWs and treatment works treating domestic sewage. New and existing POTWs (i.e., municipal facilities). New and existing concentrated animal feeding operations (CAFOs) and aquatic animal production facilities. Existing industries discharging process wastewater. New industries discharging process wastewater. New and existing industries discharging non-process wastewater only. New and existing industries discharging stormwater. New and existing industries with cooling water intake structures. New and existing POTWs and other treatment works treating domestic sewage (covers sludge).]

[Form or request: 1 .... Form 1 | 2 .... Form 2A | 3 .... Form 2B | 4 .... Form 2C | 5 .... Form 2D | 6 .... Form 2E | 7 .... Form 2F | 8 .... 40 CFR 122.21(r) and 122.22(d) | 9 .... Form 2S]

[Table IV—EPA NPDES Permit Application Forms by Applicant Type]

[Form or request: New and existing applicants, except POTWs and treatment works treating domestic sewage. New and existing POTWs (i.e., municipal facilities). New and existing concentrated animal feeding operations (CAFOs) and aquatic animal production facilities. Existing industries discharging process wastewater. New industries discharging process wastewater. New and existing industries discharging non-process wastewater only. New and existing industries discharging stormwater. New and existing industries with cooling water intake structures. New and existing POTWs and other treatment works treating domestic sewage (covers sludge).]

[Form or request: 1 .... Form 1 | 2 .... Form 2A | 3 .... Form 2B | 4 .... Form 2C | 5 .... Form 2D | 6 .... Form 2E | 7 .... Form 2F | 8 .... 40 CFR 122.21(r) and 122.22(d) | 9 .... Form 2S]

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[Form or request: 1 .... Form 1 | 2 .... Form 2A | 3 .... Form 2B | 4 .... Form 2C | 5 .... Form 2D | 6 .... Form 2E | 7 .... Form 2F | 8 .... 40 CFR 122.21(r) and 122.22(d) | 9 .... Form 2S]
procedures (or approved alternative test procedures).

In 2008 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. 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 those forms were contained in separate ICRs. 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 proposed rule, EPA also assessed the cost information for 40 CFR 136 methods found in the National Environmental Methods Index (NEMI) at 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 reported results, 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. We request comment on this assessment of the cost range for the various EPA-approved methods. We acknowledge 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 proposed rule is expected to result in little or no new or increased burden to applicants or permittees. We request comment on the burden estimate resulting from this proposal.

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.

V. 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.

VI. Statutory and Executive Order Reviews

A. Executive Order 12866: Regulatory Planning and Review

This rule is not a “significant regulatory action” under the terms of Executive Order 12866 (58 FR 51735, October 4, 1993) and is therefore not subject to review under the EO.

B. Paperwork Reduction Act

This action does not impose any new information collection burden. This proposed rulemaking merely clarifies testing procedures under the NPDES program based on existing legal requirements and authorities. The proposed rulemaking requires the use of sufficiently sensitive analytical test methods when applying for an NPDES permit and when performing sampling and analysis pursuant to monitoring requirements in an NPDES permit. However, 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 IV (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 proposed 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 proposed rule on small entities, I certify that this action will not have a significant economic impact on a substantial number of small entities. Because EPA is simply clarifying, based on existing legal requirements and authorities, that sufficiently sensitive analytical test methods must be used when applying for an NPDES permit and when performing sampling and analysis pursuant to monitoring requirements in an NPDES permit, this proposed action will not impose any new legally binding requirements or burden on EPA, States, or the regulated community, and specifically, any burden on any small entity. EPA continues to be interested in the potential impacts of the proposed rule on small entities and welcomes comments on issues related to such impacts.

D. Unfunded Mandates Reform Act

This proposed 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. EPA is proposing to clarify under existing legal requirements and authorities that sufficiently sensitive analytical test methods may be used when applying for an NPDES permit and when performing sampling and analysis pursuant to monitoring requirements in an NPDES permit. The rulemaking will not impose any new legally binding requirements on EPA, States, or the regulated community. Thus, this proposed rule is not subject to the requirements of sections 202 and 205 of the UMRA. For the same reason, EPA has determined that this rule contains no regulatory requirements that might significantly or uniquely affect small governments. Thus, this proposed rule is not subject to the requirements of section 203 of UMRA.

E. Executive Order 13132: Federalism

This proposed rule does not have federalism implications. If 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 government, as specified in Executive Order 13132 (64 FR 43255, August 10, 1999). This proposed rule does not change the relationship between the national government and the States or change their roles and responsibilities. Rather, this proposed rulemaking would confirm Agency policy, which is based on existing legal requirements and authorities, that sufficiently sensitive analytical test methods must be used 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 proposed 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. In the spirit of Executive Order 13132, and consistent with EPA policy to promote communications between EPA and State and local governments, EPA specifically solicits comment on this proposed action from State and local officials.

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

This proposed 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 proposed rule, which is based on existing legal requirements and authorities, clarifies that sufficiently sensitive analytical test methods must be used when applying for an NPDES permit and when performing sampling and analysis pursuant to monitoring requirements in an NPDES permit. Nothing in this proposed rule would prevent an Indian Tribe from exercising its own organic authority to deal with such matters. EPA specifically solicits additional comment on this proposed action from Tribal officials.

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

The proposed rule is not subject to Executive Order 13045, “Protection of Children from Environmental Health Risks and Safety Risks” (62 FR 19985, 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. This proposed rule only interprets existing legal requirements and authorities and clarifies Agency policy that sufficiently sensitive analytical test methods must be used when applying for an NPDES permit and when performing sampling and analysis pursuant to monitoring requirements in an NPDES permit.

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 a significant regulatory action under Executive Order 12866.

I. National Technology Transfer and Advancement Act

Section 12(d) of the National Technology Transfer and Advancement Act (NNTAA) 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 NNTAA directs EPA to provide explanations to Congress, through OMB, when the Agency decides not to use available and applicable voluntary consensus standards. This proposed rulemaking does not involve technical standards. The proposed rulemaking does, however, clarify Agency policy based on existing regulations and authorities that sufficiently sensitive analytical test methods must be used when applying for an NPDES permit and when performing sampling and analysis pursuant to monitoring requirements in an NPDES permit.

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

Executive Order (EO) 12898 (59 FR 7629 (Feb. 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 and environmental effects of their programs, policies, and activities on minority populations and low-income populations in the United States.

EPA has determined that this proposed 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. This proposed rule only interprets existing legal requirements and authorities and clarifies Agency policy as stated above.
PART 122—EPA ADMINISTERED PERMIT PROGRAMS: THE NATIONAL POLLUTANT DISCHARGE ELIMINATION SYSTEM

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


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) 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 in accordance with another method 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 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;

(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;

(C) The method has the lowest ML of the analytical methods approved under 40 CFR part 136.

(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, or otherwise required by the Director, the applicant may use any suitable, sufficiently sensitive method but shall provide a description of the method that includes documentation of the ML.

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 in accordance with another method 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;

(2) The method ML is above the level of the effluent limit in the permit, but the amount of the pollutant or pollutant parameter in a facility’s discharge is high enough that the method detects and quantifies the amount of the pollutant or pollutant parameter in the discharge;

(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 sufficiently sensitive 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:


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, when more than one test procedure is available under this part for the analysis of a pollutant or pollutant parameter, the test procedure selected shall be sufficiently sensitive as defined at 40 CFR 122.21(e)(3) and 122.44(i)(1)(iv).