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ORAL ARGUMENT SCHEDULED FOR MAY 9, 2011

IN THE UNITED STATES COURT OF APPEALS
FOR THE DISTRICT OF COLUMBIA CIRCUIT

No. 09-1001, with Nos. 09-1010, 1076 & 1115, *Consolidated*

LAKE CARRIERS' ASSOCIATION, et al., Petitioner,
v.
LISA JACKSON, ADMINISTRATOR, UNITED STATES ENVIRONMENTAL PROTECTION AGENCY, and UNITED STATES ENVIRONMENTAL PROTECTION AGENCY, Respondents.

ON PETITION FOR REVIEW OF FINAL ACTION OF THE UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

RESPONDENTS' FINAL BRIEF

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DATED: March 29, 2011

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CERTIFICATE AS TO PARTIES, RULINGS, AND RELATED CASES

A. Certificate as to Parties, Intervenors, and Amicus Curiae

Petitioners' Certificate accurately lists the Parties, Intervenors, and an *amicus curiae* – Nutech O3, Inc. – in this case. After Petitioners filed their initial Brief, the State of New York filed a notice of intent to file an amicus curiae brief in this case.

B. Ruling under Review

Petitioners accurately identify the agency action under review.

C. Related Cases

Respondent agrees with Petitioners that these consolidated cases have not previously been before this Court, and that these consolidated cases have been severed from Case Nos. 09-1089, 09-1131, 09-1135, 09-1162, 09-1163. Respondents are unaware of any other related cases, as that term is defined in Circuit Rule 28(a)(1)(C).

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GLOSSARY

APA	Administrative Procedure Act, 5 U.S.C. §§ 551-559, 701-706
CWA	Clean Water Act, 33 U.S.C. §§ 1255-1387
EPA	Petitioner United States Environmental Protection Agency
JA	Joint Appendix
Lake Carriers	Petitioner Lake Carriers' Association and its co-petitioners the American Waterways Operators and the Canadian Shipowners Association
MDEQ	Michigan Department of Environmental Quality
NPDES	National Pollutant Discharge Elimination System
RFA	Regulatory Flexibility Act, 5 U.S.C. §§ 601-612
RTC	Response to Comments

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JURISDICTION

These three consolidated petitions for review, brought by trade associations against Respondents the United States Environmental Protection Agency ("EPA") and its Administrator, Lisa Jackson in her official capacity, concern EPA's issuance of a general permit pursuant to the Clean Water Act (the "CWA" or "Act"), 33 U.S.C. §§ 1251-1387, for certain discharges from vessels.

EPA took final action on the challenged permit (the "Vessel General Permit") pursuant to its authority under CWA section 402(a), 33 U.S.C. § 1342(a). 73 Fed. Reg. 79,473 (Dec. 29, 2008). EPA agrees with Petitioner Lake Carriers' Association and its co-petitioners the American Waterways Operators and the Canadian Shipowners Association (collectively "Lake Carriers" or "Petitioners") that the petitions were timely filed and that this Court has jurisdiction pursuant to CWA section 509(b)(1)(F), 33 U.S.C. § 1369(b)(1)(F).[1]

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[1] Several environmental organizations and the State of Michigan also filed petitions for review challenging the Vessel General Permit, but those cases (consolidated *sub nom. Natural Resources Defense Council v. EPA*, No. 09-1089) have been severed from this one and are being held in abeyance, pending further order of this Court, to allow the parties in those cases time to finalize a likely settlement. Certain of those environmental petitioners have intervened in this case on EPA's behalf. In addition, the State of New York has filed a notice of intent to file an *amicus curiae* brief in this case on March 1, 2011, when the intervenors' brief is also due. The *amicus curiae* brief filed by Nutech O3, Inc. does not address (or even purport to address) issues presented in Lake Carriers' Brief and should be disregarded by the Court.

STATEMENT OF ISSUES

1. Whether EPA was required to subject the final Vessel General Permit to an additional round of notice and comment where neither the CWA nor EPA's regulations contemplate such procedure.

2. Whether – assuming EPA was not required to take notice and comment on the final Vessel General Permit – EPA was nonetheless "obligated to study" whether state-devised permit conditions that EPA is required by CWA section 401, EPA regulations, and applicable case law to incorporate into the final Permit, create "formidable" "burdens" on the shipping industry.

3. Whether Petitioners waived arguments that (a) EPA erred by not making the "certification" required under CWA section 401, and (b) EPA failed to comply with the Regulatory Flexibility Act, because neither Petitioners nor any other party presented these arguments to EPA during the applicable comment period.

4. Whether, notwithstanding CWA section 401's clear language authorizing States in which a pollution discharge originates to "certify" that such discharge will comply with applicable CWA and state requirements, EPA was required to make such certification "itself."

5. Whether EPA was required to consider state-devised permit

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conditions in EPA's Economic Analysis under the Regulatory Flexibility Act in issuing the final Vessel General Permit where those permit conditions are not subject to APA § 553(b)'s requirement to publish a notice of proposed rulemaking.

STATUTES AND REGULATIONS

Most of the pertinent statutes and regulations are included in Petitioners' Addendum. Those not included in Petitioners' Addendum are attached hereto.

STATEMENT OF THE CASE

A. CWA Statutory/Regulatory Background

Clean Water Act section 301(a), 33 U.S.C. § 1311(a) provides that "the discharge of any pollutant by any person shall be unlawful" unless the discharge complies with certain other sections of the Act. The CWA defines "discharge of a pollutant" as "(A) any addition of any pollutant to navigable waters from any point source, (B) any addition of any pollutant to the waters of the contiguous zone or the ocean from any point source other than a vessel or other floating craft." 33 U.S.C. § 1362(12). A "point source" is a "discernible, confined and discrete conveyance," and includes a "vessel or other floating craft." Section 502(14), 33 U.S.C. § 1362(14). "Pollutant" includes, among other things, "garbage," "chemical wastes," and "industrial, municipal, and agricultural waste discharged

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into water."[2]

A person may discharge a pollutant without violating section 301's prohibition by obtaining authorization to discharge (referred to herein as "coverage") under a National Pollutant Discharge Elimination System ("NPDES") permit issued pursuant to section 402, 33 U.S.C. § 1342. Under that provision, EPA may "issue a permit for the discharge of any pollutant, or combination of pollutants, notwithstanding section 1311(a)" upon certain conditions.

NPDES permits are either "individual" or "general." An individual permit authorizes a specific entity to discharge a pollutant in a specific place and is issued pursuant to procedures specified in EPA regulations. 40 C.F.R. §§ 122.21, 124.1-124.21, 124.51-124.66. A general permit may be issued under certain circumstances for an entire class of known and/or unknown dischargers pursuant to similar administrative permit issuance procedures. *Id.* §§ 122.28, 124. A general permit typically allows discharges to commence only upon receipt by the permitting agency of a notice of intent to discharge, but that requirement may be

[2] The definition of "pollutant" excludes "sewage from vessels or a discharge incidental to the normal operation of a vessel of the Armed Forces" within the meaning of section CWA section 312, 33 U.S.C. § 1322.

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waived at the permit issuer's discretion. *Id.* § 122.28(b)(2)(iv).[3]

Under the CWA, each State sets its own water quality standards, subject to EPA's review and approval. *See* section 303, 33 U.S.C. § 1313; 40 C.F.R. §§ 131.4, 131.10-131.12. In order to approve a State's proposed standards, EPA must be satisfied that the standards comply with CWA requirements. 33 U.S.C. § 1313(a).

Before EPA can issue a general or individual NPDES permit, each State, Tribal area, or Territory[4] in which the discharges originate (or will originate) must certify – or waive its right to certify – that the discharges authorized by the permit will comply with the State's water quality standards ("CWA section 401 certification"). CWA section 401(a); 40 C.F.R. §§ 122.4(b), 124.53.[5] Such

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[3] Whichever authorization method is used, the permit issuer can require a particular discharger to undergo the individual permit application process. *Id.* § 122.28(b)(3).

[4] Although the regulations at 40 C.F.R. §§ 124.53-.55 refer only to "States," applicable EPA regulations define "State" to mean "any of the 50 States, the District of Columbia, Guam, the Commonwealth of Puerto Rico, the Virgin Islands, American Samoa, the Commonwealth of the Northern Mariana Islands, the Trust Territory of the Pacific Islands, or an Indian Tribe as defined in these regulations which meets the requirements of §123.31 of this chapter." 40 C.F.R. § 122.2. Hereafter, this brief will refer to States, Tribes and Territories collectively as "States."

[5] Section 401(a) specifies that the State certify that the discharge will comply with

(continued...)

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certifications "shall set forth any effluent limitations and other limitations, and monitoring requirements" necessary to assure compliance with water quality standards and other appropriate requirements of state law and such conditions and requirements "shall become a condition on any Federal license or permit." CWA section 401(d), 33 U.S.C. § 1341(d). EPA's regulation at 40 C.F.R. § 124.55(a) provides that "no final permit shall be issued" (1) if certification is "denied," or (2) unless "the final permit incorporates the requirements" specified in the certification pursuant to 40 C.F.R. § 124.53(e).

STATEMENT OF FACTS

A. Exclusion Of Vessels From NPDES Permitting

Shortly after the CWA's enactment, EPA promulgated a regulation excluding from NPDES permitting discharges "incidental" to the "normal operation" of vessels. 38 Fed. Reg. 13,528 (May 22, 1973). Six years later, EPA promulgated final revisions to the regulation. 44 Fed. Reg. 32,854 (June 7, 1979.) That form of the regulation, in effect for almost 30 years, provided:

The following discharges do not require NPDES permits:

[5/](...continued)
the "applicable provisions" of CWA §§ 1311, 1312, 1313, 1316, and 1317, which set out requirements for effluent limitations and water quality standards. 33 U.S.C. § 1341(a)(1).

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> (a) Any discharge of sewage from vessels, effluent from properly functioning marine engines, laundry, shower, and galley sink wastes, or any other discharge incidental to the normal operation of a vessel.

40 C.F.R. § 122.3(a).[6]

B. Legal Challenge To The Vessels Exclusion

In 1999, various parties concerned about ballast water discharges submitted a rulemaking petition to EPA asking it to repeal 40 C.F.R. § 122.3(a). *See* 73 Fed. Reg. at 79,475. The petition asserted that EPA lacked authority to exclude point source discharges from vessels from the NPDES program, and that ballast water must be regulated under that program because it contains invasive plant and animal species as well as other materials of concern (*e.g.*, oil, chipped paint, and toxins in ballast water sediment). *Id.*

In denying the petition in 2003, EPA did not contest that aquatic invasive species in ballast water cause significant environmental impacts. *Id.* at 79,476. Rather, EPA pointed to other programs that had been enacted specifically to address the issue and stated EPA's view that the CWA did not provide an

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[6] The exclusion did not apply to "rubbish, trash, garbage, or other such materials discharged overboard; nor to other discharges when the vessel is operating in a capacity other than as a means of transportation such as when used as an energy or mining facility, a storage facility or a seafood processing facility, or when secured to a storage facility or a seafood processing facility, or when secured to the bed of the ocean, contiguous zone or waters of the United States for the purpose of mineral or oil exploration or development." 40 C.F.R. § 122.3(a).

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appropriate framework for addressing ballast water and other discharges incidental to the normal operation of non-military vessels. *Id.*

Several environmental organizations brought suit in district court under the Administrative Procedure Act ("APA"), 5 U.S.C. §§ 551-559, 701-706, challenging both EPA's original promulgation of the exclusion in 40 C.F.R. § 122.3(a) and its denial of the administrative petition to repeal the exclusion. On liability, the court held on summary judgment that the exclusion exceeded EPA's CWA authority. *Northwest Envtl. Advocates v. EPA*, No. 03-05760, 2005 U.S. Dist. LEXIS 5373 (N.D. Cal. Mar. 30, 2005). On remedy, the court issued an order providing that the exclusion would be "vacated" as of September 30, 2008. *Northwest Envtl. Advocates v. EPA*, No. 03-05760, 2006 U.S. Dist. LEXIS 69476 (N.D. Cal. Sept. 18, 2006).

The Ninth Circuit upheld the lower court's decisions on liability and remedy. *Northwest Envtl. Advocates v. EPA*, 537 F.3d 1006 (9th Cir. 2008). The Court of Appeals noted that the district court had required EPA "to perform a substantial task – to bring the discharges previously exempted by § 122.3(a) within the permitting process of the CWA." *Id.* at 1026. Explaining that ballast water presented a "difficult pollution problem," the Ninth Circuit stated: "Neither the district court nor this court underestimates the magnitude of the task." *Id.* The

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court added that it anticipated that EPA "will take advantage of the flexibility of the NPDES permitting process," and took "judicial notice" that EPA had indicated that "'use of general permit(s) would appear to be an attractive possibility.'" *Id.* at 1026-27 (citation omitted).

After the appeal, at EPA's request the district court twice extended the date for the exclusion's vacatur: initially from September 30, 2008 to December 19, 2008, and subsequently until February 6, 2009.[7] After that, discharges incidental to the normal operation of vessels previously excluded from NPDES permitting – except discharges from certain types of vessels exempted from permitting by two July 2008 statutes (*see* discussion *infra*) – were subject to CWA section 301's prohibition against discharging into "waters of the United States" unless covered under an NPDES permit.[8]

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[7] During the district court proceedings on remedy, EPA asked the court to leave the exclusion in place for an extended period of time, but that request was denied.

[8] "Waters of the United States" is defined in 40 C.F.R. § 122.2 as certain inland waters and the territorial seas, which extend to the reach of the three-mile "territorial sea," as defined in CWA section 502(8). The CWA does not require NPDES permits for vessels or other floating craft operating as a means of transportation beyond the territorial seas, *i.e.*, in the contiguous zone or ocean as defined by CWA sections 502(9), (10), 33 U.S.C. §§ 1362(9), (10). *See* 33 U.S.C. § 1362(12) and 40 C.F.R. §122.2 (definition of "discharge of a pollutant"). The Vessel General Permit, therefore, does not apply in such waters.

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C. The Vessel General Permit

The Vessel General Permit was issued in direct response to the judicial ruling vacating EPA's regulation excluding from NPDES permitting discharges incidental to the normal operation of a vessel.[9] 73 Fed. Reg. at 79,473. EPA estimated that the Vessel General Permit would affect approximately 61,000 domestically-flagged commercial vessels and approximately 8,000 foreign-flagged vessels.[10] *Id.* at 79,481.

1. EPA's Notice Soliciting Information On Vessel Discharges

As an initial response to the district court's vacatur order, EPA provided early notice of its intent to begin developing NPDES permits for discharges

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[9] Lake Carriers complains (Br. 12-13) about the somewhat accelerated process for EPA's issuance of the Vessel General Permit, but in its comment letter (at 4) JA 0712, Lake Carriers stated that the schedule for issuing the Permit was "not the Agency's fault" and that "the Courts' rulings leave the EPA no choice but to speed full ahead into largely uncharted waters." *See also* Lake Carriers' comment letter at 6 ("The Court rulings have put us all in an impossible position.") (JA 0714).

[10] According to data published by the U.S. Army Corps of Engineers in its annual Waterborne Transportation Lines of the United States report (USACE, 2005a), 41,028 U.S.-flagged cargo and passenger commercial vessels were operating in United States waters at the end of 2005. The vast majority (78%) of these vessels primarily operate in the Mississippi River System and Gulf Intracoastal Waterway; 21% operate along the Atlantic, Pacific, and Gulf Coasts; and just over 1% mainly ply the Great Lakes. These data include self-propelled (*e.g.*, tankers, towboats, dry cargo) and non-self-propelled (*e.g.*, barges) vessels. Data on foreign commercial vessels (representing 83 different countries) was more limited. *See* Permit Fact Sheet (Doc. 437) at 10-11 (JA 0935-36).

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incidental to the normal operation of vessels. 72 Fed. Reg. 34,241 (June 21, 2007). EPA requested information and technical input on matters such as sources that would help identify, categorize and describe the numbers and types of commercial and recreational vessels operating in United States waters and that may have discharges incidental to normal operations. EPA received responses from commercial fishing representatives and shipping groups, environmental and outdoor recreation groups, individual citizens, the oil and gas industry, recreational boating-related businesses, and state governments. 73 Fed. Reg. at 79,474. EPA used the responses and other information to develop two draft vessel general permits. *Id.*

2. The Proposed General Permits

EPA published two draft vessel general permits for public comment on June 17, 2008. 73 Fed. Reg. 34,296. The proposed "Vessel General Permit" covered all commercial and non-recreational vessels, and recreational vessels 79 feet or longer. The proposed "Recreational General Permit" was intended to cover recreational vessels shorter than 79 feet, but soon after proposal, Congress enacted two statutes that affected the universe of vessels to be covered by general permit.

First, on July 29, 2008, the "Clean Boating Act of 2008" was signed into law (Pub. L. No. 110-288), providing that recreational vessels not be subject to the

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requirement to obtain an NPDES permit to authorize discharges incidental to their normal operation. Due to this legislation, EPA did not finalize the proposed Recreational General Permit. 73 Fed. Reg. at 79,473. EPA modified the proposed Vessel General Permit, which included recreational vessels over 79 feet long, to eliminate that coverage.

The second piece of legislation, Pub. L. No. 110-299, was signed into law on July 31, 2008. It imposed a two-year moratorium during which neither EPA nor States could generally require NPDES permits for discharges incidental to the normal operation of non-recreational vessels less than 79 feet long and commercial fishing vessels of any length.[11] EPA revised the final Vessel General Permit to reflect the new law. *Id.*

In announcing the proposed Vessel General Permit, EPA established a 45-day comment period, ending August 1, 2008. EPA's draft Vessel General

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[11] The moratorium – which did not extend to ballast water or discharges that EPA or a State determines contribute to a violation of water quality standards or pose unacceptable health or environmental risks – initially ran for two years beginning July 31, 2008, during which time EPA was to study the discharges and report to Congress. EPA issued the report, *Study of Discharges Incidental to Normal Operation of Commercial Fishing Vessels and Other Non-Recreational Vessels Less Than 79 Feet*, in August 2010. On July 30, 2010, President Obama signed P.L. No. 111-215 into law, extending the moratorium to December 18, 2013. As a result, discharges incidental to the normal operation of commercial fishing vessels and non-recreational vessels under 79 feet long are generally not currently subject to NPDES permitting.

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Permit docket registered more than 170 comment submissions from an array of stakeholders (including Petitioners), raising a wide range of technical, policy, legal, and implementation issues that EPA considered in finalizing the Vessel General Permit. 73 Fed. Reg. at 79,474.

3. The Final Vessel General Permit

EPA issued the final Vessel General Permit pursuant to its permitting authority under 33 U.S.C. § 1342 and its implementing regulations. *See, e.g.*, 40 C.F.R. Part 122 ("EPA Administered Permit Programs: The National Pollutant Discharge Elimination System").[12] The Vessel General Permit covers vessel discharges into waters of the United States in all States, regardless of whether a State is authorized to implement other aspects of the NPDES permit program within its jurisdiction, except as otherwise excluded by Part 6 of the permit.[13]

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[12] The Vessel General Permit is effective in every State and in all Indian Country Land except Taos Pueblo Tribal Lands (New Mexico).

[13] While pursuant to section 402(c), 33 U.S.C. § 1342(c), EPA typically suspends permit issuance in authorized States, EPA issued NPDES permits in such States for discharges incidental to the normal operation of a vessel because section 402(c)(1) prohibits EPA from issuing permits in authorized States only for "those discharges subject to [the state's authorized] program." Discharges excluded under 40 C.F.R. § 122.3 were not "subject to" authorized state programs; rather, vessel discharges under the Vessel General Permit were *excluded* from NPDES permitting programs. Therefore the discharges were not part of any currently authorized state NPDES program. *See* 40 C.F.R. § 123.1(i)(2) (where state

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EPA Permit Fact Sheet at 9 (JA 0934).

The Permit addresses all vessels operating in a capacity as a means of transportation (except recreational vessels) that have discharges incidental to their normal operations into waters subject to the Permit. With respect to (1) any size commercial fishing vessels (as defined in 46 U.S.C. § 2101a), and (2) non-recreational vessels less than 79 feet in length, the coverage under the Permit is limited to ballast water discharges only. 73 Fed. Reg. at 79,477.

General requirements are found in Parts 1 through 4 of the final Permit. Part 1 contains general conditions, descriptions of authorized and ineligible discharges, and an explanation of who must file a notice of intent to receive permit coverage; Part 2 discusses effluent limits and related requirements applicable to vessels; Part 3 lists required corrective actions that permittees must take to remedy deficiencies and violations; and Part 4 lists visual monitoring, self-inspection, and recordkeeping and reporting requirements. EPA Permit (Doc. No. 436) (JA 0758). Other sections of the Vessel General Permit identify select categories of vessel types that have supplemental requirements (Part 5), describe and incorporate

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[13/](...continued)
programs have greater scope of coverage than "required" under federal program, that additional coverage is not part of authorized program), and § 123.1(g)(1) (authorized state programs not required to prohibit point source discharges exempted under 40 C.F.R. § 122.3). EPA Permit Fact Sheet at 9 (JA 0934).

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additional certification requirements and conditions imposed by States under CWA section 401 (Part 6),[14] and include definitions, forms for certain reports, and forms for notice of termination and notice of intent to discharge (Parts 7-15). *Id.*

Discharges eligible for coverage under the Vessel General Permit are those incidental to the normal operation of a vessel covered by the exclusion in 40 C.F.R. § 122.3(a) prior to vacatur of that exclusion, *e.g.*, discharges such as deck runoff, bilgewater, and ballast water. The Permit establishes effluent limitations to control a variety of materials in seven major categories: aquatic nuisance species (also known as "invasive species"); nutrients; pathogens (including E. coli & fecal coliform); oil and grease; metals; conventional pollutants (biochemical oxygen demand, pH, total suspended solids); and other toxic and non-conventional pollutants with toxic effects.[15] EPA Permit Fact Sheet (JA 0937).

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[14] As evidenced by its Prayer for Relief (Br. 57-58), Lake Carriers' challenge is limited to Part 6 of the Vessel General Permit.

[15] Aquatic nuisance species – the focus of the lawsuit that led to the exclusion's vacatur – are introduced into United States waters through a variety of vectors (including ballast water and sediment from ballast tanks, chain lockers, anchor chains, and vessel hulls). Nuisance species can outcompete native species, threaten endangered species, damage habitat, change food webs, alter the chemical and physical aquatic environment, and harm recreational and commercial fisheries, infrastructure, and water-based recreation and tourism.

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4. The Vessel General Permit and the Regulatory Flexibility Act

Although EPA does not believe that the Regulatory Flexibility Act, 5 U.S.C. §§ 601-612 ("RFA"), applies to issuance of the Vessel General Permit, EPA performed an Economic Analysis of the Permit, including examining its potential economic impact on small businesses. 73 Fed. Reg. at 79,480. EPA concluded that while the Permit would have a minimal economic impact on all entities, including small businesses, the Permit is not likely to have a significant economic impact on a substantial number of small entities. *Id.* at 79,481.

SUMMARY OF ARGUMENT

In issuing the final Vessel General Permit, EPA properly incorporated into Part 6 of the Permit the CWA section 401 certification conditions submitted by States to protect their state water quality. The CWA, EPA's regulations and applicable case law in this Circuit and elsewhere uniformly support EPA's refusal to overrule those state conditions, as well as EPA's decision not to subject the final Permit to another round of notice and comment. This Court should reject Petitioners' argument that EPA should have deviated from its established permit issuance process in order to accommodate Petitioners' unsupported and speculative claims of harm from Part 6 of the Vessel General Permit.

With respect to the RFA, Petitioners waived claims relating to that statute

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by not raising them with specificity during the comment period. In any event, Vessel General Permit Part 6 is not subject to the RFA because EPA is not required to publish a notice of proposed rulemaking in connection with the CWA section 401 certification conditions. Under section 401, the public participation process is carried out at the state, not federal, level, and consideration of the state-submitted conditions would have been futile because EPA lacks authority to affect those conditions.

STANDARD OF REVIEW

This Court's review of EPA's issuance of the Vessel General Permit is governed by the APA's deferential standard. EPA's action is valid unless "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 5 U.S.C. § 706(2)(A). This standard "is a narrow one," under which the Court is not "to substitute its judgment for that of the agency." *Citizens to Preserve Overton Park, Inc. v. Volpe*, 401 U.S. 402, 416 (1971). Rather, the Court must ensure that the agency's decision was based upon relevant factors and not a "clear error of judgment." *Id.* Greater deference is given to an agency with regard to factual questions involving scientific matters in its area of technical expertise. *See Baltimore Gas & Electric Co. v. NRDC*, 462 U.S. 87, 103 (1983).

Judicial deference to an agency's decision extends to the agency's

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interpretation of a statute it administers. *Chevron, U.S.A. v. NRDC*, 467 U.S. 837, 842-45 (1984). In reviewing the agency's construction of such a statute, this Court must first decide "whether Congress has directly spoken to the precise question at issue." *Id.* at 842-43. "[I]f the statute is silent or ambiguous with respect to the specific issue, the question for the Court is whether the agency's answer is based on a permissible construction of the statute." *Id.* at 843. Here, to uphold EPA's interpretation of the CWA, the Court need not find that EPA's interpretation is the only permissible construction that EPA might have adopted, but only that EPA's interpretation is rational. *Chem. Mfrs. Ass'n v. NRDC*, 470 U.S. 116, 125 (1985). When the interpretation involves reconciling conflicting policies committed by the statute to an agency's expertise, deference is particularly appropriate. *Chevron*, 467 U.S. at 844.

Further, EPA's interpretation of its regulations governing the NPDES program is entitled to deference. *See Arkansas v. Oklahoma*, 503 U.S. 91, 110, 112 (1992). In considering the lawfulness of such an interpretation, the interpretation should be given "'controlling weight unless it is plainly erroneous or inconsistent with the regulation.'" *Thomas Jefferson Univ. v. Shalala*, 512 U.S. 504, 512 (1994) (citation omitted).

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ARGUMENT

I. EPA WAS NOT OBLIGATED TO SUBJECT THE FINAL VESSEL GENERAL PERMIT TO AN ADDITIONAL ROUND OF NOTICE AND COMMENT UNDER APA SECTION 553

A. EPA Acted Consistently With CWA Section 401, EPA's Regulations, And Applicable Case Law.

The CWA's "objective" is to "restore and maintain the chemical, physical, and biological integrity of the nation's waters." Section 101(a), 33 U.S.C. § 1251(a). To meet that objective, the Act provides that it is "the policy of the Congress" to "recognize, preserve, and protect the primary responsibilities and rights of States to prevent, reduce, and eliminate pollution," § 1251(b), and thereby "anticipates a partnership between the States and Federal Government." *Arkansas v. Oklahoma*, 503 U.S. at 101. In the CWA, "Congress plainly intended an integration of both state and federal authority." *Keating v. FERC*, 927 F.2d 616, 622 (D.C. Cir. 1991).

The federal-state partnership is exemplified by state water quality standards that implement the CWA's key substantive requirements and establish protected uses, specific water quality criteria, and anti-degradation policies. These standards, which are adopted by States in conformity with the CWA and EPA's regulations, and are subject to EPA approval, may be more (but not less) stringent than those

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required by federal law. 33 U.S.C. §§ 1313, 1370; 40 C.F.R. § 131.10. *See also Keating*, 927 F.2d at 622 (under CWA, States remain the "prime bulwark in the effort to abate water pollution," and "Congress expressly empowered them to impose and enforce water quality standards that are more stringent than those required by federal law.") (citation omitted). Although the standards are state law, after approval by EPA they "are part of the federal law of water pollution control." *Arkansas v. Oklahoma*, 503 U.S. at 110.

One way in which state water quality standards are applied to federally licensed projects or activities is through the "certification" requirements in CWA section 401, 33 U.S.C. § 1341, which assigns important authority to the States.[16] Section 401(a) provides in relevant part: "Any applicant for a Federal license or permit to conduct any activity including, but not limited to, the construction or operation of facilities, which may result in any discharge into the navigable waters, shall provide the licensing or permitting agency a certification from the State in which the discharge originates or will originate."[17] *See Keating,* 927 F.2d

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[16] The other way is through the CWA's requirement that EPA include in NDPES permits conditions as necessary to ensure compliance with applicable water quality standards. *See* 33 U.S.C. §§ 1311(b)(1)(C), 1342(a)(1); 40 C.F.R. § 122.4(d).

[17] Conversely, a State's denial of certification precludes issuance of the federal license or permit. *See* section 401(a), 33 U.S.C. § 1341(a)(1) ("No license or

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at 622 ("Although federal licenses are required for most activities that will affect water quality, an applicant for such a license must first obtain state approval of the proposed project."). Section 401(a) requires each State to "establish procedures for public notice in the case of all applications for certification by it, and to the extent it deems appropriate, public hearings in connection with specific applications." 33 U.S.C. § 1341(a).

The language in section 401 is mandatory in nature. Certifications that States provide to the federal licensing or permitting agency "*shall* set forth any effluent limitations and other limitations, and monitoring requirements" specified by States as necessary to assure compliance with water quality standards and other appropriate requirements of state law, and such conditions and requirements "*shall* become a condition on any Federal license or permit." Section 401(d), 33 U.S.C. § 1341(d) (emphasis added).

As the agency charged with the CWA's administration, EPA has promulgated rules specifically interpreting and applying § 401 to NPDES permits. *See* 40 C.F.R. §§ 124.53-.55. Most fundamentally, 40 C.F.R. § 124.53(a) provides that, pursuant to CWA section 401(a)(1), EPA may not issue a permit until

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permit shall be granted if certification has been denied").

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certification is granted or waived by the State "in which the discharge originates or will originate."

EPA's regulations set out the process to be followed. For permits, 40 C.F.R. § 124.53(c) provides that if EPA has not received the state certification before a "draft permit" is prepared, EPA (through its Regional Administrators) must send the certifying state agency: (1) a copy of the draft permit; (2) a statement that EPA cannot issue or deny the permit until the certifying state agency has granted or denied certification, or waived its right to certify; and (3) a statement that the State will be deemed to have waived its right to certify unless that right is exercised within a specified "reasonable time not to exceed 60 days" from the date the draft permit is mailed to the State, unless EPA finds that "unusual circumstances" require more time.

40 C.F.R. § 124.53(e)(1) requires that state certifications be in writing and include conditions that the State deems necessary to "assure compliance" with applicable CWA provisions and "appropriate requirements" of state law. 40 C.F.R. § 124.53(e)(2) provides that in certifying the draft permit, the State must specify "any conditions more stringent than those in the draft permit" that the State

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finds "necessary to meet the requirements" in § 124.53(e)(1).[18] Section 124.55(a) provides that "no final permit shall be issued" (1) if certification is "denied," or (2) unless "the final permit incorporates the requirements" specified in the certification pursuant to § 124.53(e).

Finally, 40 C.F.R. § 124.55(e) specifies where and how certifications can (and cannot) be challenged: "Review and appeals of limitations and conditions attributable to State certification shall be made through the applicable procedures of the State and may not be made through the procedures in this part."[19]

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[18] EPA has explained the provision limiting state CWA section 401 certification conditions to those that are "more stringent" than those in the federal draft permit as follows: "State certification rights proceed from the authority of States under section 510 of the Act to set more stringent limitations than those required by the Act.. States may not require EPA to disregard or downgrade Federal requirements." 44 Fed. Reg. 32,930 (June 7, 1979) (commenting on language of what is now codified at 40 C.F.R.§ 124.55(c)).

[19] Shipping companies, including Lake Carriers, have availed themselves of the opportunity to challenge state certification conditions in state judicial proceedings. For example, in *Port of Oswego Auth. v. Grannis,* 897 N.Y.S.2d 736 (N.Y.App.Div. 2010), the New York Supreme Court, Appellate Division, held that state standards encompassed in New York's certification conditions for the Vessel General Permit imposed "reasonable restrictions intended to reduce the unintentional discharge of invasive aquatic species and other pathogens, thereby protecting the State's waters from the harm that such species and pathogens inflict." *Id.* at 1103. That court found that the CWA "specifically permits a state to add conditions to its Vessel General Permit certification that set forth additional restrictions and limitations to ensure that federal permittees will comply with the Act as well as the applicable state laws." *Id.* Also, Lake Carriers filed an appeal

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Here, EPA requested certification from the state certifying agencies, many of which (including Illinois, Indiana, Michigan and New York) sought and received extensions of time to complete the certification process. Thereafter, the state agencies submitted their certifications to EPA, which added the states' conditions to the Vessel General Permit in Part 6, as required by CWA section 401. During the public comment period on EPA's draft Vessel General Permit, these Petitioners acknowledged that the CWA authorizes States to add conditions to the Permit. For example, in its comment letter (at 2) (JA 0710), Lake Carriers stated: "The States (Indian countries and territories as well) have the right to add their own requirements to the General Permit."

In its final form, the Vessel General Permit (Part 6) incorporated all section 401 effluent or other limitations and monitoring requirements deemed necessary by States to assure that the final Permit complies with all applicable CWA requirements and with any other appropriate requirements of state law. As

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of Pennsylvania's section 401 certification with that State's Environmental Hearing Board after the Vessel General Permit was issued. (Penna. EHB Dkt. No. 2009-003-L). That administrative appeal was settled in December 2010, and Pennsylvania modified its section 401 certification, with the result that several of its section 401 certification conditions were deleted from the Vessel General Permit. 75 Fed. Reg. 76,984 (Dec. 10, 2010). Other States deleting conditions at Petitioners' members' request include: Iowa (*see* 75 Fed. Reg. 76,984), and New Jersey, Illinois, and California (*see* 74 Fed. Reg. 10,573 (March 11, 2009)).

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expressly contemplated under CWA section 401(d), the additional limitations and monitoring requirements became enforceable conditions of the Vessel General Permit.[20] *Id.*

In seeking permit certification from the States and attaching the States' certification conditions to the final Vessel General Permit, EPA acted consistently not only with CWA section 401 and EPA's implementing regulations, but with applicable case law. In one of this Court's decisions addressing section 401, *City of Tacoma v. FERC*, 460 F.3d 53, 67 (D.C. Cir. 2006), the Court explained that the CWA gives States a "primary role" to regulate permitted discharges that can affect "local" waters, by specifically authorizing the States to impose and enforce "water quality standards that are more stringent than applicable federal standards." This Court explained that under CWA section 401, the "role" of the federal license or permit issuer "is limited to awaiting, and then deferring to, the final decision of the state." 460 F.3d at 67.

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[20] Twenty-five States submitted additional permit requirements in their section 401 certifications: California, Connecticut, Florida, Georgia, Hawaii, Idaho, Illinois, Indiana, Iowa, Kansas, Maine, Massachusetts, Michigan, Minnesota, Missouri, Nebraska, Nevada, New Hampshire, New York, Ohio, Pennsylvania, Rhode Island, Utah, Vermont and Wyoming. Two Tribes (Bishop Paiute and Hualapai) and one territory (Guam) also submitted additional requirements with their section 401 certifications for the Vessel General Permit. States, Tribes and Territories not listed above either have certified the Permit without conditions or waived certification.

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Similarly, in *Keating*, which involved state section 401 certification of a permit issued under CWA section 404, 33 U.S.C. § 1344, this Court stated that it did not "doubt the propriety of a federal agency's refusal to review the validity of a state's decision to grant or deny a request for certification." 927 F.2d at 622. *See also U.S. Dep't of Interior v. FERC*, 952 F.2d 538, 548 (D.C. Cir. 1992) (federal licensing agency may not "alter or reject" conditions imposed by States "through section 401 certificates").

The Second Circuit's decision in *American Rivers, Inc. v. FERC*, 129 F.3d 99, 107 (2d Cir. 1997), is consistent with this Court's decisions in *City of Tacoma*, *Keating*, and *United States Dep't of Interior v. FERC*. In *American Rivers*, FERC had refused to incorporate certification conditions imposed by the State of Vermont on FERC's license for a hydroelectric power facility located on a branch of the White River, which runs through that State. Petitioner American Rivers' challenge to FERC's refusal was, in the court's words, "straightforward, resting on statutory language." *Id.* at 106. American Rivers argued that "the plain language of § 401(d) indicates that FERC has no authority to review and reject the substance of a state certification or the conditions contained therein and must incorporate into its licenses the conditions as they appear in state certifications." *Id.* After noting that CWA section 401(d) leaves "little room" for FERC to argue

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that it has authority to reject even state conditions that FERC finds to be *ultra vires*, the court stated that to the extent FERC contended that Congress "intended to vest it with authority to reject 'unlawful' state conditions," FERC faced "a difficult task" since it is generally assumed that the legislature expresses its purposes through the "ordinary meaning" of the words it uses and the statutory language in section 401(d) was not just "mandatory" but "clear." *Id.* at 107. The court then rejected any notion that FERC, as a federal licensing or permitting agency, possessed "a roving mandate to decide that substantive aspects of state-imposed conditions are inconsistent with the terms of § 401." 129 F.3d at 110-11. State certification conditions, the court added, are reviewable only in state judicial tribunals with appropriate jurisdiction. *Id.* at 112.[21]

Other judicial decisions are in accord. In *Ackels v. EPA*, 7 F.3d 862, 867 (9th Cir. 1993), which involved EPA-issued gold placer mining permits in Alaska, the court stated that "once the state added the additional conditions" under section 401, "EPA was required to incorporate those conditions into the final permit and lacked authority to reject them." Petitioners' "only recourse," the court explained,

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[21] This Court has cited *American Rivers* with approval. *See Ala. Rivers Alliance v. FERC*, 325 F.3d 290, 293 (D.C. Cir. 2003) (citing *American Rivers* and stating: "Any limitations included in the state certification become a condition on the federal license.").

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was to "challenge the state certification in state judicial proceedings." *Id.*

Roosevelt Campobello International Park Comm'n v. EPA, 684 F.2d 1041 (1st Cir. 1982), which involved a permit for construction of an oil refinery and associated deepwater terminal in Maine, is also instructive. That court stated that section 401 "empowers" the State to certify that a proposed discharge will comply with the CWA and "with any other appropriate requirement of State law," and that "[a]ny such requirement 'shall become a condition on any Federal license or permit.'" 684 F.2d at 1056. The First Circuit explained that EPA "has interpreted this provision broadly to preclude federal agency review of state certification." *Id.* After citing several EPA administrative opinion letters affirming that limitations contained in state certifications must be included in NPDES permits, the court pointed to EPA regulations specifying that review and appeals of state certification conditions be made through applicable state procedures, and added:

> The courts have consistently agreed with this interpretation, ruling that the proper forum to review the appropriateness of a state's certification is the state court, and that federal courts and agencies are without authority to review the validity of requirements imposed under state law or in a state's certification.

Id.

The *Roosevelt Campobello* court added that its conclusion that EPA "lacked authority to review the conditions imposed by the State of Maine" was supported

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by the statutory scheme. The court noted that CWA section 510 "specifically preserves" a State's right to "'adopt or enforce . . . any requirement respecting control or abatement of pollution,' even if it is more stringent than those adopted by the federal government." 684 F.2d at 1056.

Notwithstanding section 401's straightforward language, Lake Carriers argues that EPA violated APA § 553 by attaching the state-submitted conditions to the draft Vessel General Permit without subjecting the final Permit to another round of notice and comment. Lake Carriers asserts (Br. 24) that because the draft Permit preceded the States' submission of certification conditions, the "regulated community" was unable to provide EPA with comments on the conditions "both in terms of how they interact with each other and how they relate to the Vessel General Permit as a whole, before including them as federally enforceable requirements in the Vessel General Permit."[22]

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[22] Lake Carriers also makes much of the fact that certain parties were dissatisfied by having to certify (in the case of some States) or comment on (in the case of some regulated parties) the draft Vessel General Permit in the relatively compressed time frame that EPA was able to allow prior to vacatur of the permitting exclusion. Lake Carriers (Br. 10-11) quotes from one State's letter asserting that CWA section 401(a)(1) provides States one full year to complete the certification process. Lake Carriers fails to acknowledge that the statute does not support that assertion. Rather, section 401(a)(1) specifies that if a State fails or refuses to act on a certification request "within a reasonable period of time (which *shall not exceed one year*)" (emphasis added) after receipt of such request, the

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However, EPA's approach was entirely consistent not only with the Act but with EPA's longstanding regulations interpreting and implementing section 401. Pursuant to those regulations, *see* 40 C.F.R. § 124.10(a)(ii), EPA gives public notice and provides opportunity for comment on *draft* NPDES permits – including the Vessel General Permit – prepared under § 124.6(d). EPA's regulations do not require EPA to subject the final Vessel General Permit with the added state conditions to another round of notice-and-comment.

EPA regulations also provide that unless state certification has already been "received by the time the *draft* permit is issued," EPA "shall send the certifying State agency" a "copy of a *draft* permit." 40 C.F.R. § 124.53(c)(1) (emphasis added). The regulations then provide that the State "will be deemed to have waived its right to certify" unless it exercises that right "within a specified reasonable time not to exceed 60 days" from the date the "*draft* permit" is mailed to the certifying state agency (unless EPA "finds that unusual circumstances require a longer time."). *Id.* § 124.53(c)(3) (emphasis added). Under 40 C.F.R. §

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certification requirements are "waived." And, EPA regulations provide that the State "will be deemed to have waived its right to certify" unless it exercises that right "within a specified reasonable time not to exceed 60 days," unless that period is extended. 40 C.F.R. § 124.53(c). To accommodate these concerns, EPA extended the certification deadline for a number of States, allowing more than three additional months in some circumstances.

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124.53(e), the State's certification of the "*draft* permit" is to include "any conditions more stringent than those in the *draft* permit which the State finds necessary" to assure compliance with "applicable provisions" of the CWA and "appropriate requirements of State law." And, under § 124.55(a)(1)&(2), unless the "final permit incorporates the requirements specified in the certification," "no final permit shall be issued." In sum, nothing in EPA's section 401 regulations contemplates, let alone requires, that EPA re-submit a permit to the certifying States or seek comment on a final permit after the state conditions have been included.

Lake Carriers' argument is an unusual one. Lake Carriers does not contend that EPA did not follow its regulations, but that EPA failed to *deviate* from them or, in Lake Carriers' phrasing, to "alter the process" for issuing the certified permit. (Br. 41.) Similarly, in its comment letter (at 17) (JA 0725), Lake Carriers acknowledged that it wanted EPA to "create" a new "notice and comment process at the Federal level" for the Vessel General Permit. After stating, "We understand that Section 401 Certification is part of the Clean Water Act and unlikely able to be altered by EPA in a regulatory process," Lake Carriers asserted that "EPA has the discretion to and should modify the Section 401 Certification Program to require States wishing to impose additional requirements to propose those

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additional requirements through the EPA and the Federal rulemaking process." *Id.* *See also* comment letter from Lake Carriers' co-Petitioner American Waterways Operators (EPA Doc. 343.1 at 5) (JA 0641) (stating that "we understand that 401 certification is a requirement of the Clean Water Act and is unlikely to be altered"). Petitioners have never petitioned EPA to revise its regulations, however.

As EPA pointed out in response to this argument during the comment period, if Lake Carriers believes that EPA's section 401 regulations need to be revised, Lake Carriers must file an administrative petition with the Agency seeking such revisions, which could be accomplished only through a separate notice-and-comment rulemaking. EPA Doc. 438 at 14-13 (JA 1064). Lake Carriers cannot mount a challenge to EPA's longstanding section 401 regulations in this proceeding.

B. The APA Does Not Require EPA To Provide An Additional Round Of Notice And Comment On Vessel General Permit Part 6, Which Includes The Section 401 Certification Conditions.

Although the exact certification process that Lake Carriers believes EPA should have followed is unclear, it appears to be arguing that EPA was obligated under the APA to: prepare a draft Vessel General Permit; submit it to the States; allow not just the 60 days specified in the regulations but much longer (apparently a full year) for the certifying agencies to complete certification; re-publish the

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draft Permit with those certification conditions attached; take comment from "the regulated community" (and perhaps others) on the "entire" Vessel General Permit "package"; "review and address concerns" (*id.* 24) expressed by commenters; reject any state conditions that are "conflicting, confusing, illegal or unconstitutional" (*id.*); and publish the final Vessel General Permit without the offending conditions.[23]

Lake Carriers fundamentally errs in contending that APA section 553 applies in this instance. That provision applies only to rulemakings and EPA's issuance of the Vessel General Permit is not a rulemaking.[24] But even if the

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[23] Lake Carriers does not say but, presumably, if EPA were to follow Lake Carriers' suggestion and strike from the Vessel General Permit those state conditions that EPA found objectionable, Lake Carriers would object were EPA to re-submit the revised "entire permit package" to the States for a second round of certification. Under such a process, States might "re-certify" the very conditions that EPA had deleted, or even add new ones, presumably re-triggering another supposedly mandatory opportunity for regulated parties to comment on the Vessel General Permit. It is obvious from this that Lake Carriers wants the last word on the Permit, but that is not contemplated by the CWA or by EPA's regulations; nor is it mandated by the APA.

[24] EPA is aware of this Court's decision in *National Ass'n of Homebuilders v. U.S. Army Corps of Engineers*, 417 F.3d 1272, 1284 (D.C. Cir. 2005), holding that the general permit in that case – issued by the U.S. Army Corps of Engineers, not EPA, pursuant to CWA section 404 rather than 402 – fit within the APA's definition of "rule." EPA respectfully disagrees with that decision, but recognizes that the *Homebuilders* decision might bind this panel if it were required in this case to reach the issue of whether the Vessel General Permit is likewise a "rule." EPA believes that, for the reasons set forth in this brief, the Court need not reach

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Permit were a rulemaking, EPA was not required to subject the Permit to a second round of notice and comment. Certainly, Lake Carriers never explains how its desired approach is consistent with the CWA or EPA's regulations.

But inherent in Lake Carriers' demand for an additional round of public comment is the notion that EPA not only has *authority* to review the merits of the States' certification conditions, EPA is *obligated* to review those conditions and reject those that might (in Lake Carriers' words – Br. 37) "potentially" be "conflicting, confusing and problematic." After all, it would be pointless to require EPA to take comment on conditions that, as explained above, EPA lacked statutory authority to revise or delete. As the court stated in *NRDC v. EPA*, 279 F.3d 1180, 1186 (9th Cir. 2002) – cited by Lake Carriers (Br. 31) – a fundamental purpose of notice and comment procedures is to provide interested parties an opportunity to "offer comments that could persuade the agency to modify its rule." (Citation omitted.) Here, however, EPA lacks authority to modify the Vessel General Permit by rejecting or altering any of the conditions to which Lake Carriers objects.

[24/](...continued)
that issue here. EPA notes its disagreement with the *Homebuilders* decision specifically to preserve the issue in the event that *en banc* review becomes necessary regarding the issue of whether the Vessel General Permit challenged here fits within the APA's definition of a rule.

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In an attempt to buttress its claim that EPA was required to comply with the APA and take comment on the final Vessel General Permit with state conditions attached, Lake Carriers (Br. 31-34) leans heavily on the Ninth Circuit's *NRDC* decision, but that case does not advance Lake Carriers' cause. *NRDC* involved a challenge by environmental petitioners to EPA general permits authorizing the operators of log transfer facilities in Alaska to release bark and other woody debris into marine waters. Such debris can accumulate and "create problems for marine life and worsen the quality of the water." *Id.* at 1184.

After EPA found that existing log transfer facility permits did not comply with the CWA, EPA proposed to modify all pre-1985 permits for such facilities in Alaska and issued for comment draft general permits that would apply to nearly all of them. In accordance with Alaska's guideline for implementing its water quality standards, the draft general permits allowed a one-acre "zone of deposit" for the woody debris. *Id.* As required by CWA section 401 and EPA regulations, EPA sought certification from Alaska before it finalized the general permits. The State engaged in a public process on its draft certifications, which resulted in a certification that would place no size limits on zones of deposit. *Id.* at 1185. Although EPA initially expressed concern that this change made the requirements less stringent and thus might run afoul of CWA anti-degradation requirements,

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EPA ultimately decided that permits without the proposed zone of deposits would ensure compliance with Alaska's water quality standards and issued the final general permits without the draft permits' one-acre limit. *Id.* at 1187-88.

Referring to this change as a "paradigm shift," the *NRDC* court held that EPA had erred by not affording notice and soliciting further comments on the final permits. *Id.* at 1188. In so ruling, however, the court made clear the limited nature of its ruling:

> To be sure, the EPA does not act as a reviewing agency for state certification, and the proper forum for review of state certification is through applicable state procedures.

Id. The court stated that the issue before it was not state certification but "EPA's independent statutory obligation under the CWA to ensure *compliance with water quality standards*" and "its power to impose *additional* permit conditions to meet that end." *Id.* at 1188 (emphasis added). *See also* 33 U.S.C. §§ 1311(b)(1)(C), 1342(a)(1); 40 C.F.R. §122.4(d).

Lake Carriers' claims here differ from those advanced by the environmental petitioners in NRDC in at least two fundamental ways. First, Lake Carriers does not – and could not – complain that EPA changed its own water-quality based effluent limits as a result of new information provided by a State regarding its interpretation of its water quality standards (which happened to be reflected in the

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State's CWA section 401 certification) without affording the public the opportunity to weigh in on EPA's judgment. Lake Carriers' concern is with conditions EPA has clearly identified as being issued solely pursuant to the state § 401 certification process. In addition, unlike the environmental petitioners in *NRDC* – who were concerned that Alaska's conditions made EPA's general permits impermissibly *less* stringent – Lake Carriers demands that EPA take notice and comment on which state conditions EPA should overrule as *too* stringent, notwithstanding that pursuant to CWA section 401, each certifying State has the right to add those conditions to the Vessel General Permit to protect water quality in that State. Given that EPA lacks authority to overrule state conditions on the ground that they are too stringent, EPA cannot be held to be obligated under the APA (or any other statute) to subject the Vessel General Permit to another round of notice and comment in order to allow the "regulated community" opportunity to advise EPA which state conditions EPA should review and reject.

While not a CWA case, this Court's decision in *Asiana Airlines v. FAA*, 134 F.3d 393 (D.C. Cir. 1998), is instructive. At issue there was whether the FAA acted lawfully in employing an expedited procedure which precluded notice and comment before the effective date of an interim final rule. The statute in question – 49 U.S.C. § 45301(b)(2) – specifically directed the FAA to publish as an

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"interim final rule" an initial fee schedule for certain air traffic control and other services, "pursuant to which public comment will be sought and a final rule issued." *Id.* at 395. The FAA acknowledged that it issued the interim final rule without public notice and comment and did not invoke the "good cause" exception to normal APA procedures, but relied on the statute's procedural directive as "subsequent and specific authority" that trumped the otherwise applicable APA § 553. 134 F.3d at 396. The FAA interpreted the statute's express directive as obviating the usual first step of providing notice of a proposed rule.

This Court agreed with the FAA that it did not need to conform to APA § 553 procedures, finding that Congress "provided express direction" to the agency by "specifying procedures which differ from those of the APA." 134 F.3d at 398. As this Court explained, the FAA was to issue not a "proposed" rule but an "interim final" rule, and to seek comment "pursuant to," not in "anticipation of," that rule. *Id.* This Court held that although Congress did not "speak as clearly" as it had in other circumstances, the language before it still "plainly expresses a congressional intent to depart from normal APA procedures." *Id.* As this Court described it, the question is "whether Congress has established procedures so clearly different from those required by the APA that it must have intended to displace the norm." *Id.* at 397.

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Here, in section 401(a) & (d), Congress mandated that the certifying state agency "establish procedures for public notice in the case of all applications for certification by it, and to the extent it deems it appropriate, procedures for public hearings in connection with specific applications," and provided that all resulting certifications "shall become a condition on any Federal license or permit" subject to the provisions of section 401. These provisions furnish an alternative process to § 553, first by shifting the procedural public participation requirements to the State, and second by relegating EPA to the essentially ministerial role of incorporating all state certification conditions into the permit. Section 401, in this Court's phrasing, evinces a "congressional intent to depart from normal APA procedures." EPA, which took public comment on the draft Permit, was not required in this situation to subject the final Vessel General Permit with certification conditions to another round of notice and comment pursuant to APA § 553.

Thus, Lake Carriers' focus on whether the Vessel General Permit is a logical outgrowth of the draft permit misses the mark. Furthermore, even assuming that APA § 553 applies, the test for whether an agency has run afoul of that provision is whether a new round of notice and comment would provide the first opportunity for interested parties to offer comments that could persuade the

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agency to modify its rule. *Am. Water Works Ass'n v. EPA*, 40 F.3d 1266, 1274 (D.C. Cir. 1994). The courts therefore focus on whether the purposes of notice and comment have been adequately served. *Fertilizer Inst. v. EPA*, 935 F.2d 1303, 1311 (D.C. Cir. 1991). Given that EPA lacks authority to reject state section 401 conditions submitted to it, further notice and comment from Lake Carriers (or others) protesting that EPA should overrule the certification conditions or "alter" the certification process would be to no avail.

The CWA and EPA's implementing regulations contemplate that EPA will prepare and submit to the States for certification a draft NPDES permit, and will finalize the permit by attaching to it all conditions properly submitted by the certifying States (unless those conditions would make the permit less stringent). Contrary to Lake Carriers' suggestion (Br. 30), EPA did not "pull a surprise 'switcheroo' on regulated entities" when it issued the final Vessel General Permit. Lake Carriers was aware from EPA's regulations that the Agency was obligated to incorporate the certification conditions into the permit and would do so without an additional round of notice-and-comment. Whether Lake Carriers was able to anticipate with precision every condition that States submitted to EPA for addition to the Permit during the certification process is beside the point.

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C. Even If APA § 553 Did Apply, Petitioners Have Failed To Show Prejudice Here.

Even if APA § 553 did apply, APA § 706 contemplates that Petitioners show prejudice from an agency procedural shortcoming. *See City of Waukesha v. EPA*, 320 F.3d 228, 246 (D.C. Cir. 2003). This Court has held that in making such a showing in the context of an alleged violation of notice-and-comment requirements, petitioners "may be required to demonstrate that, had proper notice been provided, they would have submitted additional, different comments that could have invalidated the rationale for the revised rule." *Id. See also Shell Oil Co. v. EPA*, 950 F.2d 741, 752 (D.C. Cir. 1991).

Lake Carriers fails to establish that it was deprived of a meaningful opportunity to offer its views on the potential requirements that shippers might face once state conditions were incorporated into the Vessel General Permit. Although Lake Carriers acknowledges (Br. 33) it was "generally aware" that "EPA would seek section 401 certification of the Vessel General Permit," it claims that it "could not have possibly anticipated the substance of a patchwork" of the "more stringent" state conditions that resulted. Yet in its comment letter (at 17), Lake Carriers articulated that very concern, in strikingly similar language:

> Section 401 Certification is likely to result in a myriad of differing requirements from State to State. This patchwork quilt of

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> requirements taken in conjunction with Federal requirements under the Vessel General Permit and already existing federal laws and statutes applying to a number of these discharges will create a potential conflict among the various Federal and State requirements that will make compliance impossible.

As Lake Carriers itself recognizes (Br. 13-14), EPA did not ignore such comments, but responded – accurately – that it lacks authority to reject state section 401 certification conditions, and that it was each State's obligation, not EPA's, to provide for public participation concerning specific conditions.

Even now, after having full knowledge of the state conditions that have been incorporated into the Vessel General Permit (in Part 6), and actually operating pursuant to the conditions for over one and one-half years, Lake Carriers offers only equivocal and speculative support for its contention that EPA should have acted inconsistently with section 401 and deviated from its regulations by taking public comment on which state conditions EPA should overrule. Lake Carriers asserts, for example, that "it *might be* impossible to comply with one condition without violating another" (Br. 21, emphasis added), and that "there *appears* to be an inherent conflict" in the Vessel General Permit regarding New York's and Michigan's conditions such that a vessel "may well" (*id.* 23, emphasis added) be faced with conflicting requirements. *See also* Br. 24 (referring to "apparently conflicting" section 401 requirements; *id.* 37 (Permit has effect of

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"potentially" creating "conflicting, confusing and problematic state requirements"); *id.* 39 (Permit conditions impose "potentially" conflicting certification requirements for vessels in transit); *id.* 42 (Permit's "varied requirements" "perhaps" "make it impossible to comply with one condition without violating another"); *id.* 45 (citing an "apparent conflict" between New York and Michigan requirements); *id.* 49 (Permit's conditions are "potentially inconsistent"); *id.* 49 (Permit "appears" to require that "some regulated entities violate one provision of the permit in order to comply with another").

Lake Carriers offer a lengthy, but irrelevant, discourse (*id.* 16-21) on how a "vessel traveling the nation's waters can be subject to dozens of different vessel discharge requirements along a single voyage," and complains that it was "never given a chance to explain how and why" these "varied requirements" would create "very practical compliance issues, the burden that they placed on interstate commerce, and how it *might* be impossible to comply with one condition without violating another." (*Id.* 20-21, emphasis added.) Lake Carriers should direct its argument on this score to Congress – which provided for such broad state autonomy in the CWA – not to EPA or the courts.

Although Lake Carriers alludes to the notion that shippers face "impossible" compliance dilemmas, the example it provides does not support even its equivocal

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claim that "there *appears* to be an inherent conflict in the final Vessel General Permit that makes it impossible for a vessel capable of discharging ballast water to transit New York and discharge in Michigan waters without violating the Vessel General Permit." (Br. 21, emphasis added.) There is simply no basis for concluding that a vessel cannot meet the requirements of both States' section 401 certifications. When in New York waters, a vessel must have and operate a system that meets New York's standards as specified in its section 401 certification (*see* EPA Doc. 436, Part 6.22 (JA 0843), and when in Michigan waters, a vessel's ballast water discharge must meet the prescribed chlorite limits (if the vessel uses a chlorine or chlorine-dioxide based system). *Id.* Part 6.15 (JA 0838). Contrary to Lake Carriers' suggestion (Br. 23), these requirements do not require that a ballast water discharge into non-New York waters must meet the standards stated in New York's certification; nor do they impose a duty to operate such a system outside New York State waters. And even if New York's certification conditions did apply in Michigan waters – which they do not – it is pure speculation to assume that if a vessel has an installed ballast water treatment system that meets New York's limits, it cannot meet Michigan's limits for total residual chlorine or

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chlorite for its discharge of ballast water.[25]

Further, Lake Carriers' concerns about "serious potential liability" that it claims is the result of these "apparently conflicting section 401 requirements" are unfounded at present. The New York ballast water standards in question do not apply to any vessels at this time, because vessels are not required to have a ballast water treatment system that meets New York's standards until January 1, 2012. *See* EPA Doc. 436, Part 6.22 (JA 0847). And even then, New York's section 401 certification allows permittees to request an extension of that implementation date. In fact, members of all three Petitioner organizations sought – and the State of New York granted on February 7, 2011 – an extension for compliance until August 1, 2013.

Lake Carriers' argument also ignores that the potential for conflicting regulatory requirements as vessels move from one State's waters to another's is inherent in the CWA's structure, which in section 510 "specifically preserves" a state's right to "'adopt or enforce . . . any requirement respecting control or abatement of pollution,' even if it is more stringent than those adopted by the federal government." 33 U.S.C. § 1370. Thus, even in the absence of section 401

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[25] The Court should disregard the non-record "chart" submitted by Lake Carriers' as "Exh. 1" to its Brief (referenced at Br. 21, 45).

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certification, States are free to regulate discharges, including ballast water and other vessel discharges, without regard to whether neighboring States impose different requirements that potentially complicate matters for shipping companies. In fact, Michigan, California, Washington, and other States have enacted statutes and regulations regulating ballast water discharges in the waters of those States, and those laws apply to discharges by Lake Carriers' members even in the absence of section 401.[26]

For example, Michigan amended its Natural Resources and Environmental Protection Act, Mich. Comp. Laws § 324.101 *et seq.*, in 2005 to require oceangoing vessels "engaging in port operations in" Michigan waters to obtain a permit from the Michigan Department of Environmental Quality ("MQEQ"), beginning January 1, 2007. *Id.* § 324.3112(6). MDEQ may issue such a permit only if the applicant can demonstrate that the vessel will not "discharge aquatic nuisance species or if the oceangoing vessel discharges ballast water or other waste or waste effluent, that the operator of the vessel will utilize environmentally sound technology and methods," as determined by MDEQ, "that can be used to

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[26] *See* Cal. Code Regs. tit. 2, §§ 2291-2297.1; Wash. Admin. Code §§ 220-150-010 to 220-150-180.

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prevent the discharge of aquatic nuisance species." *Id.*[27]

II. EPA WAS NOT OBLIGATED UNDER THE APA TO "REVIEW AND ADDRESS" LAKE CARRIERS' CONTENTIONS THAT INCORPORATION OF STATE CERTIFICATION CONDITIONS INTO THE VESSEL GENERAL PERMIT WOULD RENDER THE PERMIT "CONFLICTING, CONFUSING, ILLEGAL OR UNCONSTITUTIONAL"

In addition to attacking EPA for failing to take comment on the final Vessel General Permit with state conditions attached, Lake Carriers advances a second procedural argument – *i.e.*, that EPA "failed to review and address concerns" over whether the conditions added to the final Permit were "conflicting, confusing, illegal or unconstitutional." (Br. 24, Section VII.C). Although Lake Carriers begins this argument (Br. 42) by reiterating its contention that EPA did not afford it an additional opportunity to comment on "how and why" the Permit's "varied requirements" would create "compliance issues" or "perhaps" make it "impossible to comply with one condition without violating another," Lake Carriers then acknowledges that EPA had "before it concerns over the prospect that those

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[27] A coalition of shipping companies challenged the constitutionality of Michigan's Ballast Water Statute. After the United States District Court dismissed the suit, the Sixth Circuit upheld that ruling on appeal, rejecting arguments – similar to those advanced here by Lake Carriers – that Michigan's statute is preempted by federal law and violates the Commerce Clause or the Fourteenth Amendment's Due Process clause. *Fednav, Ltd. v. Chester*, 547 F.3d 607 (6th Cir. 2008).

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requirements would be likely to present serious problems" (Br. 42), undercutting its first procedural argument.

Lake Carriers then asserts (Br. 48) that EPA was "obligated to study this important aspect of the problem before issuing the final Vessel General Permit" but "failed to do so." Lake Carriers confuses matters by obscuring whether its argument is substantive or merely procedural, asserting that "*the issue* here is the *process* used by EPA in issuing the Vessel General Permit *and* the *validity* of the entire package of requirements." (Br. 48-49, emphases added). Although Lake Carriers proceeds (Br. 49-53) to assert that the Permit might infringe on due process by "appearing" to require that "some" regulated entities "violate one provision of the permit in order to comply with another" and creates constitutional "issues," Lake Carriers ultimately sums up its argument as follows: "Accordingly, EPA has an *obligation to review* the requirements submitted by the various States to ensure that the state requirements incorporated into a final NPDES permit do not violate the Constitution." (Br. 53, emphasis added). Thus, Lake Carriers' second argument amounts to the procedural claim that EPA failed to respond in sufficient detail to Lake Carriers' concerns, which it claims present "quite serious" issues. (Br. 44.)

The argument that EPA should have devoted substantial time and effort

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responding to Lake Carriers' contentions regarding the potential difficulties that could ensue from the Permit's incorporation of state section 401 certification conditions suffers from the same infirmity as Lake Carriers' first procedural argument. EPA is not authorized, let alone obligated, under the APA or any other statute, to overrule the merits of States' section 401 certification conditions and, therefore, EPA was not obligated to "review," let alone "perform an in-depth analysis" (Br. 41), of Lake Carriers' claims that the permit could be improved were EPA to re-write CWA section 401, "alter" the certification process (Br. 41), and overrule supposedly too-stringent or conflicting conditions submitted by the States. Lake Carriers' string-cite (Br. 43-44) to cases standing for the proposition that an agency must respond to "substantial" and "relevant" comments is beside the point.[28]

This Court's decision in *City of Portland v. EPA*, 507 F.3d 706 (D.C. Cir. 2007), is instructive. The petitioners in that case argued that EPA had failed to adequately address certain comments during the administrative process. This Court stated that whether EPA adequately responded to the comments "makes no difference because the Agency had no obligation to respond to them in the first

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[28] To the extent that Lake Carriers believes that the Vessel General Permit (or even the CWA itself) is preempted or unconstitutional, Lake Carriers could have attacked it on that basis. Its failure to do so here is telling.

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place." *Id.* at 714. This Court explained that EPA must give "reasoned responses" only to "*significant*" comments, *id.* (emphasis in original), which the Court defined as those "which, if true, raise points relevant to the agency's decision and *which, if adopted, would require a change in an agency's proposed rule.*" *Id.* at 715 (quoting *Home Box Office, Inc. v. FCC*, 567 F.2d 9, 35 n.58 (D.C. Cir. 1977)) (emphasis added by the Court). This Court went on in *City of Portland* to find the comments in question to be "insignificant" because under the statute there at issue, the comments were "incapable of affecting the final rule, and EPA could disregard them." 507 F.3d at 715. Here, Lake Carriers' comments on the States' certification conditions were inherently insignificant because EPA was bound by the statute to incorporate the conditions into the challenged Permit. EPA did not, in any event, disregard the comments. It simply, and appropriately, articulated the limits of its authority to overrule those conditions.

Lake Carriers proffers (Br. 49) a handful of cases in an effort to support its contention that EPA should override CWA section 401's mandate that federal agencies incorporate state certification conditions into the permits they issue. Fairly read, however, those cases stand merely for the unremarkable proposition that an agency should avoid interpreting statutes in ways that create constitutional issues. They do not authorize an agency to disregard an unambiguous statutory

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requirement on the ground that complying with the legislature's direction might implicate "constitutional issues." (Br. 49). Resolving such questions – assuming they are properly presented in the first place, and here they are not – is not a job for the Agency.

The extremely narrow scope of EPA's authority to review state certification conditions is illuminated by this Court's 2006 decision in *City of Tacoma.* There, FERC had issued a license for a hydroelectric project. One of the petitioners argued that FERC violated its obligations under CWA section 401 by accepting a state certification despite the certifying state agency's failure to produce records showing it gave public notice or held a public hearing with respect to its certification. 460 F.3d at 67. This Court held that FERC's role was limited to the non-substantive one of verifying – if compliance has been "called into question" – "facial" state compliance with "state public notice procedures at least to the extent of obtaining an assertion of compliance with the relevant state agency." *Id.* at 68.

Lake Carriers' procedural arguments lack merit.

III. CWA SECTION 401 DOES NOT REQUIRE EPA TO CERTIFY THE VESSEL GENERAL PERMIT IN LIEU OF THE STATES

Lake Carriers (Br. 38-39) advances an argument not raised before: that EPA erred by not making the § 401 certification "itself," supposedly "as directed by the CWA." Because neither Lake Carriers nor any other party presented this

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argument to EPA during the comment period, this argument was waived. *See Military Toxics Project v. EPA*, 146 F.3d 948, 956 (D.C. Cir. 1998) (declining to reach merits in challenge to EPA rulemaking where neither petitioners nor anyone else commented on issue during rulemaking process and therefore petitioners "waived the argument and may not raise it for the first time upon appeal"); *NRDC v. EPA*, 25 F.3d 1063, 1074 (D.C. Cir. 1994) ("We have previously held that failure to raise a particular question of statutory construction before an agency constitutes waiver of the argument in court.").

Even assuming it was not waived, the argument lacks any support in the statute. The gist of Lake Carriers' argument (Br. 38-40) is that under section 401(a), certifications are to be provided by "the State in which the discharge originates or will originate," except in a case where a State has "no authority" to give such a certification, in which case the certification "shall be from the Administrator." Citing this language, Lake Carriers argues that Congress "envisioned" that there would always be a single State (or one interstate agency in certain cases), not multiple States (or interstate agencies), making the section 401 certification for an EPA-issued permit. Lake Carriers (Br. 41, emphasis added) argues that because the Vessel General Permit is "designed to regulate the same *discharge point* as it moves from place to place," there is "no single state in which

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the discharge originates," and therefore no individual State "may issue the section 401 certification."

Lake Carriers' semantic argument is ill-founded. Section 401(a) does not utilize the term "discharge points." Rather, it focuses on the waters "where the discharge originates or will originate" and affords States the right to certify (or refuse to certify) that the "discharge" in question will comply with applicable CWA and state requirements. That a vessel might ultimately depart from one State's waters and enter another's – possibly emitting pollutants in both, through discharges "originating" in both – does not deprive each of those States of the right to protect its own waters by adding conditions to the general permit through the section 401 certification process. Neither State loses "authority" to issue certifications covering discharges originating in its waters simply because the "discharge point" (*i.e.*, the vessel) moves (or has the potential of moving) to another State's waters and also discharging there.

Lake Carriers' argument is founded on faulty logic. It asserts that (1) because there is no "single" State in which all discharges originate, (2) no individual State has authority to "issue the section 401 certification." Not only is there no logical connection between the premise and the conclusion, Lake Carriers' argument turns the section on its head. There is no reason to conclude

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that state certification authority is triggered by a discharge in a single State but extinguished entirely when the discharge occurs (or might occur) in multiple States. Indeed, the opposite conclusion – that there are then multiple States with certification authority – is a far more plausible interpretation of section 401, given that its goal is to allow States to act individually to protect the quality of their own waters. To the extent that Lake Carriers believes that the CWA allows for the "over-regulation" of vessel discharges, Lake Carriers' remedy lies with Congress, not the Agency or the courts.

IV. LAKE CARRIERS WAIVED ANY ARGUMENT THAT EPA FAILED TO COMPLY WITH THE RFA, BUT IN ANY EVENT THE RFA DOES NOT REQUIRE EPA TO CONSIDER STATE SECTION 401 CERTIFICATION CONDITIONS IN FULFILLING ANY OBLIGATIONS EPA MAY HAVE UNDER THE RFA

The Regulatory Flexibility Act ("RFA"), as amended by the Small Business Regulatory Enforcement Fairness Act of 1996, requires agencies to consider the effects of their regulatory actions on small entities. *See* 5 U.S.C. §§ 604(a), 603(b),(c). The RFA is a "[p]urely procedural" statute. *U.S. Cellular Corp. v. FCC*, 254 F.3d 78, 88 (D.C. Cir. 2001).

The RFA applies only when an agency is required either by the APA or any other law "to publish general notice of proposed rulemaking," 5 U.S.C. §§ 603(a), 604(a), in which case the RFA requires the agency to prepare an initial regulatory

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flexibility analysis unless the head of the agency "certifies" that the rule will not, if promulgated, have a "significant economic impact on a substantial number of small entities." *Id.* §§ 605(b), 603(a).

If the agency is unable to so certify, its initial regulatory flexibility analysis must describe the proposed rule's "impact" on "small entities" and the alternatives to the proposed rule that would minimize any significant economic impact of the proposed rule on such entities, while accomplishing the agency's objectives. *Id.* § 603(a),(c). In such case, the agency must also, before promulgating its final rule, prepare a final regulatory flexibility analysis. *Id.* §§ 605(b), 604(a). Among other things, that analysis must provide a description of the agency's effort to "minimize the significant economic impact on small entities," including "a statement of the factual, policy, and legal reasons for selecting the alternative adopted in the final rule and why each one of the other significant alternatives to the rule considered by the agency . . . was rejected." *Id.* § 604(a)(5).

Here, although EPA believes that the Vessel General Permit is not a "rule" and therefore is not subject to the RFA, EPA nonetheless performed an Economic Analysis of both the draft and the final Permit, including examining the Permit's potential economic impact on small businesses. *See* 73 Fed. Reg. at 79,481. EPA concluded in those analyses that the Permit is not likely to have a significant

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economic impact on a substantial number of small entities. *Id.*

Lake Carriers argues (Br. 53-54) that Part 6 of the Vessel General Permit (which includes the CWA section 401 certification conditions) is contrary to law because EPA failed to comply with the RFA. 5 U.S.C. §§ 601-612. Specifically, Lake Carriers asserts that the Permit is a rule and that EPA's conclusion that the Permit was not likely to have a significant impact on a substantial number of small entities lacked a reasoned basis because EPA failed to consider the requirements that were added to the final Permit (in Part 6) pursuant to the section 401 certification process. Lake Carriers (Br. 54) asks the Court to set aside EPA's determination.

Lake Carriers has waived its RFA argument. As this Court has stated, it is "a hard and fast rule of administrative law, rooted in simple fairness, that issues not raised before an agency are waived and will not be considered by a court on review." *Nuclear Energy Inst., Inc. v. EPA*, 373 F.3d 1251, 1297 (D.C. Cir. 2004) (per curiam); *see also Nat'l Wildlife Fed'n v. EPA*, 286 F.3d 554, 562 (D.C. Cir. 2002) (there is "near absolute bar against raising new issues – factual or legal – on appeal in the administrative context."). Courts "should not topple over administrative decisions unless the administrative body not only has erred but has erred against objection made at the time appropriate under its practice." *United*

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States v. L.A. Tucker Truck Lines, 344 U.S. 33, 37 (1952).

Although Lake Carriers knew that EPA was required to include the States' section 401 certification conditions in the Vessel General Permit, Lake Carriers failed to object to EPA's approach to determining the effect of the Permit on small entities at the appropriate time, *i.e.*, when EPA solicited comments on the proposed Vessel General Permit and provided its accompanying small business economic impact finding.[29] Lake Carriers acknowledged in its comment letter (at 17) (JA 0725) that EPA would be adding section 401 certification provisions to the Permit, but never objected to EPA's failure to address any impact of these provisions before concluding that the Permit would be unlikely to have a significant economic impact on a substantial number of small entities. In fact, although Lake Carriers strongly objected to the Economic Analysis's conclusion that the cost of compliance with the Permit would be "negligible," it based its criticism on EPA's purported failure to conduct "appropriate research and analysis as to the actual costs associated with complying with the Best Management Practices contained in the draft Vessel General Permit," *see* JA 0713 (comment

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[29] Not only do the CWA and EPA's regulations (and applicable case law) make clear that EPA was required to include the section 401 certification provisions in the final Vessel General Permit, the proposed permit contained a placeholder for section 401 certification provisions and the draft permit's Fact Sheet mentioned that section 401 certification provisions would be included in the final Permit. *See* Proposed Vessel General Permit Fact Sheet (JA 0326).

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letter at 5), and made no mention of the role it thought the looming CWA section 401 certification provisions must play in supporting EPA's final assessment of costs on small businesses. While Lake Carriers voiced numerous complaints and suggestions with regard to the yet-to-be-issued CWA section 401 certifications and how EPA should address them, Lake Carriers' view that EPA was required to factor the certifications into its final Economic Analysis for RFA purposes was not one of them.[30]

By failing to submit comments on this specific issue during the public comment period, Lake Carriers waived any right to challenge EPA's failure to consider the section 401 conditions in its RFA finding, and therefore this Court need not consider the adequacy of that finding. *See Envtl Defense Ctr, Inc. v. EPA*, 344 F.3d 832, 879 n.66 (9th Cir. 2003) (rejecting RFA challenge and noting that consideration of the RFA issue "may be gratuitous, since petitioners failed to submit timely comment disputing the adequacy of EPA's consideration of economic impacts on small businesses").

But even if Lake Carriers is deemed not to have waived the issue, Vessel

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[30] It is noteworthy that allowing for consideration of the costs associated with CWA section 401 certification provisions in EPA's RFA analysis was not among the reasons Lake Carriers gave for its insistence that EPA conduct notice and comment on these provisions "at the federal level." (Comment letter at 17). (JA 0725)

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General Permit Part 6 – which contains the section 401 certification conditions – is not subject to the RFA because EPA is not "required" by APA § 553 "or any other law" to "publish a notice of proposed rulemaking" in connection with the section 401 certification conditions. 5 U.S.C. §§ 603(a), 604(a). As discussed above, the CWA does not contemplate that the section 401 process follow the APA § 553 notice-and-comment procedures. Instead, the CWA mandates that the public participation process for these certifications be carried out at the *state* level. Because the section 401 certification process does not trigger the APA's (or any other statute's) rulemaking requirements, the RFA does not apply to those certifications. Consequently, EPA did not need to conduct an assessment of impacts on small businesses taking into account the Permit's section 401 certification provisions in Part 6. *Cf. Or. Trollers Ass'n v. Gutierrez*, 452 F.3d 1104, 1125 (9th Cir. 2006) (finding that because the National Marine Fisheries Service properly relied on "good cause" exception in connection with certain management measures, "it did not have an obligation under the RFA" to issue a regulatory flexibility analysis); *Roche v. Evans*, 249 F. Supp.2d 47, 57 (D. Mass. 2003) (finding that agency was not required to publish general notice of proposed rulemaking and concluding, therefore, that the "predicate for application of the RFA to the process is thus lacking"); *A.M.L. International, Inc. v. Daley*, 107 F.

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Supp. 2d 90 (D. Mass. 2000) (holding "interim measures" portion of fishery management plan exempt from RFA where Magnuson-Stevens Conservation and Management Act exempted such measures from notice and comment requirements).

Finally, consideration of the impacts of the section 401 certification conditions would have been futile in any event because EPA is powerless to affect those conditions and must include them in its permits. EPA could not have carried out "the intent of the [RFA] legislation that agencies give explicit consideration to a range of *alternatives* that would 'substantially' reduce the economic impact of the rule on individuals of limited means, small businesses, small organizations, and small governmental jurisdictions while meeting the goals and purposes of the governing statute." S. Rep. No. 95-1322, at 9 (1978) (emphasis added). In this context, Lake Carriers cannot demonstrate any harm traceable to EPA's decision not to conduct further analysis under the RFA. *See* 5 U.S.C. § 706 (judicial review under APA is conducted with "due account . . . of the rule of prejudicial error").

CONCLUSION

For the foregoing reasons, the consolidated Petitions should be denied.

Respectfully submitted March 29, 2011: s/ *Martin F. McDermott*

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CERTIFICATE OF COMPLIANCE

I certify that this brief complies with the type-volume limitation of Federal Rule of Appellate Procedure 32(a)(7)(B) and the typeface requirements of Rule 32(a)(5) & 32(a)(6) because it is proportionally spaced, has a 14-point font Times New Roman typeface, and contains 13,976 words, as counted by Corel WordPerfect X3, excluding the portions of the brief exempted by Fed. R. App. P. 32(a)(7)(B)(iii).

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CERTIFICATE OF SERVICE

I hereby certify that on the 29th day of March 2011, a copy of the foregoing RESPONDENTS' FINAL BRIEF was filed and served on counsel of record through the Court's CM/ECF system.

s/ *Martin F. McDermott*

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STATUTORY & REGULATORY ADDENDUM

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agency has issued a general notice of proposed rulemaking,[1] and

(3) the name and telephone number of an agency official knowledgeable concerning the items listed in paragraph (1).

(b) Each regulatory flexibility agenda shall be transmitted to the Chief Counsel for Advocacy of the Small Business Administration for comment, if any.

(c) Each agency shall endeavor to provide notice of each regulatory flexibility agenda to small entities or their representatives through direct notification or publication of the agenda in publications likely to be obtained by such small entities and shall invite comments upon each subject area on the agenda.

(d) Nothing in this section precludes an agency from considering or acting on any matter not included in a regulatory flexibility agenda, or requires an agency to consider or act on any matter listed in such agenda.

(Added Pub. L. 96–354, § 3(a), Sept. 19, 1980, 94 Stat. 1166.)

§ 603. Initial regulatory flexibility analysis

(a) Whenever an agency is required by section 553 of this title, or any other law, to publish general notice of proposed rulemaking for any proposed rule, or publishes a notice of proposed rulemaking for an interpretative rule involving the internal revenue laws of the United States, the agency shall prepare and make available for public comment an initial regulatory flexibility analysis. Such analysis shall describe the impact of the proposed rule on small entities. The initial regulatory flexibility analysis or a summary shall be published in the Federal Register at the time of the publication of general notice of proposed rulemaking for the rule. The agency shall transmit a copy of the initial regulatory flexibility analysis to the Chief Counsel for Advocacy of the Small Business Administration. In the case of an interpretative rule involving the internal revenue laws of the United States, this chapter applies to interpretative rules published in the Federal Register for codification in the Code of Federal Regulations, but only to the extent that such interpretative rules impose on small entities a collection of information requirement.

(b) Each initial regulatory flexibility analysis required under this section shall contain—

(1) a description of the reasons why action by the agency is being considered;

(2) a succinct statement of the objectives of, and legal basis for, the proposed rule;

(3) a description of and, where feasible, an estimate of the number of small entities to which the proposed rule will apply;

(4) a description of the projected reporting, recordkeeping and other compliance requirements of the proposed rule, including an estimate of the classes of small entities which will be subject to the requirement and the type of professional skills necessary for preparation of the report or record;

(5) an identification, to the extent practicable, of all relevant Federal rules which may duplicate, overlap or conflict with the proposed rule.

(c) Each initial regulatory flexibility analysis shall also contain a description of any significant alternatives to the proposed rule which accomplish the stated objectives of applicable statutes and which minimize any significant economic impact of the proposed rule on small entities. Consistent with the stated objectives of applicable statutes, the analysis shall discuss significant alternatives such as—

(1) the establishment of differing compliance or reporting requirements or timetables that take into account the resources available to small entities;

(2) the clarification, consolidation, or simplification of compliance and reporting requirements under the rule for such small entities;

(3) the use of performance rather than design standards; and

(4) an exemption from coverage of the rule, or any part thereof, for such small entities.

(Added Pub. L. 96–354, § 3(a), Sept. 19, 1980, 94 Stat. 1166; amended Pub. L. 104–121, title II, § 241(a)(1), Mar. 29, 1996, 110 Stat. 864.)

REFERENCES IN TEXT

The internal revenue laws, referred to in subsec. (a), are classified generally to Title 26, Internal Revenue Code.

AMENDMENTS

1996—Subsec. (a). Pub. L. 104–121, § 241(a)(1)(B), inserted at end "In the case of an interpretative rule involving the internal revenue laws of the United States, this chapter applies to interpretative rules published in the Federal Register for codification in the Code of Federal Regulations, but only to the extent that such interpretative rules impose on small entities a collection of information requirement."

Pub. L. 104–121, § 241(a)(1)(A), which directed the insertion of ", or publishes a notice of proposed rulemaking for an interpretative rule involving the internal revenue laws of the United States" after "proposed rule" was executed by making the insertion where those words appeared in first sentence to reflect the probable intent of Congress.

EFFECTIVE DATE OF 1996 AMENDMENT

Amendment by Pub. L. 104–121 effective on expiration of 90 days after Mar. 29, 1996, but inapplicable to interpretative rules for which a notice of proposed rulemaking was published prior to Mar. 29, 1996, see section 245 of Pub. L. 104–121, set out as a note under section 601 of this title.

§ 604. Final regulatory flexibility analysis

(a) When an agency promulgates a final rule under section 553 of this title, after being required by that section or any other law to publish a general notice of proposed rulemaking, or promulgates a final interpretative rule involving the internal revenue laws of the United States as described in section 603(a), the agency shall prepare a final regulatory flexibility analysis. Each final regulatory flexibility analysis shall contain—

(1) a succinct statement of the need for, and objectives of, the rule;

(2) a summary of the significant issues raised by the public comments in response to

[1] So in original. The comma probably should be a semicolon.

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the initial regulatory flexibility analysis, a summary of the assessment of the agency of such issues, and a statement of any changes made in the proposed rule as a result of such comments;

(3) a description of and an estimate of the number of small entities to which the rule will apply or an explanation of why no such estimate is available;

(4) a description of the projected reporting, recordkeeping and other compliance requirements of the rule, including an estimate of the classes of small entities which will be subject to the requirement and the type of professional skills necessary for preparation of the report or record; and

(5) a description of the steps the agency has taken to minimize the significant economic impact on small entities consistent with the stated objectives of applicable statutes, including a statement of the factual, policy, and legal reasons for selecting the alternative adopted in the final rule and why each one of the other significant alternatives to the rule considered by the agency which affect the impact on small entities was rejected.

(b) The agency shall make copies of the final regulatory flexibility analysis available to members of the public and shall publish in the Federal Register such analysis or a summary thereof.

(Added Pub. L. 96–354, § 3(a), Sept. 19, 1980, 94 Stat. 1167; amended Pub. L. 104–121, title II, § 241(b), Mar. 29, 1996, 110 Stat. 864.)

REFERENCES IN TEXT

The internal revenue laws, referred to in subsec. (a), are classified generally to Title 26, Internal Revenue Code.

AMENDMENTS

1996—Subsec. (a). Pub. L. 104–121, § 241(b)(1), amended subsec. (a) generally. Prior to amendment, subsec. (a) read as follows: "When an agency promulgates a final rule under section 553 of this title, after being required by that section or any other law to publish a general notice of proposed rulemaking, the agency shall prepare a final regulatory flexibility analysis. Each final regulatory flexibility analysis shall contain—

"(1) a succinct statement of the need for, and the objectives of, the rule;

"(2) a summary of the issues raised by the public comments in response to the initial regulatory flexibility analysis, a summary of the assessment of the agency of such issues, and a statement of any changes made in the proposed rule as a result of such comments; and

"(3) a description of each of the significant alternatives to the rule consistent with the stated objectives of applicable statutes and designed to minimize any significant economic impact of the rule on small entities which was considered by the agency, and a statement of the reasons why each one of such alternatives was rejected."

Subsec. (b). Pub. L. 104–121, § 241(b)(2), substituted "such analysis or a summary thereof." for "at the time of publication of the final rule under section 553 of this title a statement describing how the public may obtain such copies."

EFFECTIVE DATE OF 1996 AMENDMENT

Amendment by Pub. L. 104–121 effective on expiration of 90 days after Mar. 29, 1996, but inapplicable to interpretative rules for which a notice of proposed rulemaking was published prior to Mar. 29, 1996, see section 245 of Pub. L. 104–121, set out as a note under section 601 of this title.

§ 605. Avoidance of duplicative or unnecessary analyses

(a) Any Federal agency may perform the analyses required by sections 602, 603, and 604 of this title in conjunction with or as a part of any other agenda or analysis required by any other law if such other analysis satisfies the provisions of such sections.

(b) Sections 603 and 604 of this title shall not apply to any proposed or final rule if the head of the agency certifies that the rule will not, if promulgated, have a significant economic impact on a substantial number of small entities. If the head of the agency makes a certification under the preceding sentence, the agency shall publish such certification in the Federal Register at the time of publication of general notice of proposed rulemaking for the rule or at the time of publication of the final rule, along with a statement providing the factual basis for such certification. The agency shall provide such certification and statement to the Chief Counsel for Advocacy of the Small Business Administration.

(c) In order to avoid duplicative action, an agency may consider a series of closely related rules as one rule for the purposes of sections 602, 603, 604 and 610 of this title.

(Added Pub. L. 96–354, § 3(a), Sept. 19, 1980, 94 Stat. 1167; amended Pub. L. 104–121, title II, § 243(a), Mar. 29, 1996, 110 Stat. 866.)

AMENDMENTS

1996—Subsec. (b). Pub. L. 104–121 amended subsec. (b) generally. Prior to amendment, subsec. (b) read as follows: "Sections 603 and 604 of this title shall not apply to any proposed or final rule if the head of the agency certifies that the rule will not, if promulgated, have a significant economic impact on a substantial number of small entities. If the head of the agency makes a certification under the preceding sentence, the agency shall publish such certification in the Federal Register, at the time of publication of general notice of proposed rulemaking for the rule or at the time of publication of the final rule, along with a succinct statement explaining the reasons for such certification, and provide such certification and statement to the Chief Counsel for Advocacy of the Small Business Administration."

EFFECTIVE DATE OF 1996 AMENDMENT

Amendment by Pub. L. 104–121 effective on expiration of 90 days after Mar. 29, 1996, but inapplicable to interpretative rules for which a notice of proposed rulemaking was published prior to Mar. 29, 1996, see section 245 of Pub. L. 104–121, set out as a note under section 601 of this title.

§ 606. Effect on other law

The requirements of sections 603 and 604 of this title do not alter in any manner standards otherwise applicable by law to agency action.

(Added Pub. L. 96–354, § 3(a), Sept. 19, 1980, 94 Stat. 1168.)

§ 607. Preparation of analyses

In complying with the provisions of sections 603 and 604 of this title, an agency may provide either a quantifiable or numerical description of

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programs approved by the Administrator as adequate to assure compliance with section 405 of the CWA.

(3) The Regional Administrator may designate any person subject to the standards for sewage sludge use and disposal as a ''treatment works treating domestic sewage'' as defined in § 122.2, where the Regional Administrator finds that a permit is necessary to protect public health and the environment from the adverse effects of sewage sludge or to ensure compliance with the technical standards for sludge use and disposal developed under CWA section 405(d). Any person designated as a ''treatment works treating domestic sewage'' shall submit an application for a permit under § 122.21 within 180 days of being notified by the Regional Administrator that a permit is required. The Regional Administrator's decision to designate a person as a ''treatment works treating domestic sewage'' under this paragraph shall be stated in the fact sheet or statement of basis for the permit.

[NOTE TO § 122.1: Information concerning the NPDES program and its regulations can be obtained by contacting the Water Permits Division(4203), Office of Wastewater Management, U.S.E.P.A., Ariel Rios Building, 1200 Pennsylvania Avenue, NW., Washington, DC 20460 at (202) 260–9545 and by visiting the homepage at *http://www.epa.gov/owm/*]

[65 FR 30904, May 15, 2000, as amended at 72 FR 11211, Mar. 12, 2007]

§ 122.2 Definitions.

The following definitions apply to parts 122, 123, and 124. Terms not defined in this section have the meaning given by CWA. When a defined term appears in a definition, the defined term is sometimes placed in quotation marks as an aid to readers.

Administrator means the Administrator of the United States Environmental Protection Agency, or an authorized representative.

Animal feeding operation is defined at § 122.23.

Applicable standards and limitations means all State, interstate, and federal standards and limitations to which a ''discharge,'' a ''sewage sludge use or disposal practice,'' or a related activity is subject under the CWA, including ''effluent limitations,'' water quality standards, standards of performance, toxic effluent standards or prohibitions, ''best management practices,'' pretreatment standards, and ''standards for sewage sludge use or disposal'' under sections 301, 302, 303, 304, 306, 307, 308, 403 and 405 of CWA.

Application means the EPA standard national forms for applying for a permit, including any additions, revisions or modifications to the forms; or forms approved by EPA for use in ''approved States,'' including any approved modifications or revisions.

Approved program or *approved State* means a State or interstate program which has been approved or authorized by EPA under part 123.

Aquaculture project is defined at § 122.25.

Average monthly discharge limitation means the highest allowable average of ''daily discharges'' over a calendar month, calculated as the sum of all ''daily discharges'' measured during a calendar month divided by the number of ''daily discharges'' measured during that month.

Average weekly discharge limitation means the highest allowable average of ''daily discharges'' over a calendar week, calculated as the sum of all ''daily discharges'' measured during a calendar week divided by the number of ''daily discharges'' measured during that week.

Best management practices (''BMPs'') means schedules of activities, prohibitions of practices, maintenance procedures, and other management practices to prevent or reduce the pollution of ''waters of the United States.'' BMPs also include treatment requirements, operating procedures, and practices to control plant site runoff, spillage or leaks, sludge or waste disposal, or drainage from raw material storage.

BMPs means ''best management practices.''

Class I sludge management facility means any POTW identified under 40 CFR 403.8(a) as being required to have an approved pretreatment program (including such POTWs located in a State that has elected to assume local program responsibilities pursuant to 40 CFR 403.10(e)) and any other treatment

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works treating domestic sewage classified as a Class I sludge management facility by the Regional Administrator, or, in the case of approved State programs, the Regional Administrator in conjunction with the State Director, because of the potential for its sludge use or disposal practices to adversely affect public health and the environment.

Bypass is defined at §122.41(m).

Concentrated animal feeding operation is defined at §122.23.

Concentrated aquatic animal feeding operation is defined at §122.24.

Contiguous zone means the entire zone established by the United States under Article 24 of the Convention on the Territorial Sea and the Contiguous Zone.

Continuous discharge means a "discharge" which occurs without interruption throughout the operating hours of the facility, except for infrequent shutdowns for maintenance, process changes, or other similar activities.

CWA means the Clean Water Act (formerly referred to as the Federal Water Pollution Control Act or Federal Water Pollution Control Act Amendments of 1972) Public Law 92–500, as amended by Public Law 95–217, Public Law 95–576, Public Law 96–483 and Public Law 97–117, 33 U.S.C. 1251 *et seq.*

CWA and regulations means the Clean Water Act (CWA) and applicable regulations promulgated thereunder. In the case of an approved State program, it includes State program requirements.

Daily discharge means the "discharge of a pollutant" measured during a calendar day or any 24-hour period that reasonably represents the calendar day for purposes of sampling. For pollutants with limitations expressed in units of mass, the "daily discharge" is calculated as the total mass of the pollutant discharged over the day. For pollutants with limitations expressed in other units of measurement, the "daily discharge" is calculated as the average measurement of the pollutant over the day.

Direct discharge means the "discharge of a pollutant."

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 §123.1.) In such cases, the term "Director" means the Regional Administrator and not the State Director.

Discharge when used without qualification means the "discharge of a pollutant."

Discharge of a pollutant means:

(a) Any addition of any "pollutant" or combination of pollutants to "waters of the United States" from any "point source," or

(b) Any addition of any pollutant or combination of pollutants to the waters of the "contiguous zone" or the ocean from any point source other than a vessel or other floating craft which is being used as a means of transportation.

This definition includes additions of pollutants into waters of the United States from: surface runoff which is collected or channelled by man; discharges through pipes, sewers, or other conveyances owned by a State, municipality, or other person which do not lead to a treatment works; and discharges through pipes, sewers, or other conveyances, leading into privately owned treatment works. This term does not include an addition of pollutants by any "indirect discharger."

Discharge Monitoring Report ("DMR") means the EPA uniform national form, including any subsequent additions, revisions, or modifications for the reporting of self-monitoring results by permittees. DMRs must be used by "approved States" as well as by EPA. EPA will supply DMRs to any approved State upon request. The EPA national forms may be modified to substitute the State Agency name, address, logo, and other similar information, as appropriate, in place of EPA's.

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Standards for sewage sludge use or disposal means the regulations promulgated pursuant to section 405(d) of the CWA which govern minimum requirements for sludge quality, management practices, and monitoring and reporting applicable to sewage sludge or the use or disposal of sewage sludge by any person.

State means any of the 50 States, the District of Columbia, Guam, the Commonwealth of Puerto Rico, the Virgin Islands, American Samoa, the Commonwealth of the Northern Mariana Islands, the Trust Territory of the Pacific Islands, or an Indian Tribe as defined in these regulations which meets the requirements of §123.31 of this chapter.

State Director means the chief administrative officer of any State or interstate agency operating an "approved program," or the delegated representative of the State Director. If responsibility is divided among two or more State or interstate agencies, "State Director" means the chief administrative officer of the State or interstate agency authorized to perform the particular procedure or function to which reference is made.

State/EPA Agreement means an agreement between the Regional Administrator and the State which coordinates EPA and State activities, responsibilities and programs including those under the CWA programs.

Storm water is defined at §122.26(b)(13).

Storm water discharge associated with industrial activity is defined at §122.26(b)(14).

Total dissolved solids means the total dissolved (filterable) solids as determined by use of the method specified in 40 CFR part 136.

Toxic pollutant means any pollutant listed as toxic under section 307(a)(1) or, in the case of "sludge use or disposal practices," any pollutant identified in regulations implementing section 405(d) of the CWA.

Treatment works treating domestic sewage means a POTW or any other sewage sludge or waste water treatment devices or systems, regardless of ownership (including federal facilities), used in the storage, treatment, recycling, and reclamation of municipal or domestic sewage, including land dedicated for the disposal of sewage sludge. This definition does not include septic tanks or similar devices. For purposes of this definition, "domestic sewage" includes waste and waste water from humans or household operations that are discharged to or otherwise enter a treatment works. In States where there is no approved State sludge management program under section 405(f) of the CWA, the Regional Administrator may designate any person subject to the standards for sewage sludge use and disposal in 40 CFR part 503 as a "treatment works treating domestic sewage," where he or she finds that there is a potential for adverse effects on public health and the environment from poor sludge quality or poor sludge handling, use or disposal practices, or where he or she finds that such designation is necessary to ensure that such person is in compliance with 40 CFR part 503.

TWTDS means "treatment works treating domestic sewage."

Upset is defined at §122.41(n).

Variance means any mechanism or provision under section 301 or 316 of CWA or under 40 CFR part 125, or in the applicable "effluent limitations guidelines" which allows modification to or waiver of the generally applicable effluent limitation requirements or time deadlines of CWA. This includes provisions which allow the establishment of alternative limitations based on fundamentally different factors or on sections 301(c), 301(g), 301(h), 301(i), or 316(a) of CWA.

Waters of the United States or *waters of the U.S.* means:

(a) All waters which are currently used, were used in the past, or may be susceptible to use in interstate or foreign commerce, including all waters which are subject to the ebb and flow of the tide;

(b) All interstate waters, including interstate "wetlands;"

(c) All other waters such as intrastate lakes, rivers, streams (including intermittent streams), mudflats, sandflats, "wetlands," sloughs, prairie potholes, wet meadows, playa lakes, or natural ponds the use, degradation, or destruction of which would affect or

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exclusion does not apply to the introduction of pollutants to privately owned treatment works or to other discharges through pipes, sewers, or other conveyances owned by a State, municipality, or other party not leading to treatment works.

(d) Any discharge in compliance with the instructions of an On-Scene Coordinator pursuant to 40 CFR part 300 (The National Oil and Hazardous Substances Pollution Contingency Plan) or 33 CFR 153.10(e) (Pollution by Oil and Hazardous Substances).

(e) Any introduction of pollutants from non point-source agricultural and silvicultural activities, including storm water runoff from orchards, cultivated crops, pastures, range lands, and forest lands, but not discharges from concentrated animal feeding operations as defined in § 122.23, discharges from concentrated aquatic animal production facilities as defined in § 122.24, discharges to aquaculture projects as defined in § 122.25, and discharges from silvicultural point sources as defined in § 122.27.

(f) Return flows from irrigated agriculture.

(g) Discharges into a privately owned treatment works, except as the Director may otherwise require under § 122.44(m).

(h) The application of pesticides consistent with all relevant requirements under FIFRA (i.e., those relevant to protecting water quality), in the following two circumstances:

(1) The application of pesticides directly to waters of the United States in order to control pests. Examples of such applications include applications to control mosquito larvae, aquatic weeds, or other pests that are present in waters of the United States.

(2) The application of pesticides to control pests that are present over waters of the United States, including near such waters, where a portion of the pesticides will unavoidably be deposited to waters of the United States in order to target the pests effectively; for example, when insecticides are aerially applied to a forest canopy where waters of the United States may be present below the canopy or when pesticides are applied over or near water for control of adult mosquitoes or other pests.

(i) Discharges from a water transfer. Water transfer means an activity that conveys or connects waters of the United States without subjecting the transferred water to intervening industrial, municipal, or commercial use. This exclusion does not apply to pollutants introduced by the water transfer activity itself to the water being transferred.

[48 FR 14153, Apr. 1, 1983, as amended at 54 FR 254, 258, Jan. 4, 1989; 71 FR 68492, Nov. 27, 2006; 73 FR 33708, June 13, 2008]

§ 122.4 Prohibitions (applicable to State NPDES programs, see § 123.25).

No permit may be issued:

(a) When the conditions of the permit do not provide for compliance with the applicable requirements of CWA, or regulations promulgated under CWA;

(b) When the applicant is required to obtain a State or other appropriate certification under section 401 of CWA and § 124.53 and that certification has not been obtained or waived;

(c) By the State Director where the Regional Administrator has objected to issuance of the permit under § 123.44;

(d) When the imposition of conditions cannot ensure compliance with the applicable water quality requirements of all affected States;

(e) When, in the judgment of the Secretary, anchorage and navigation in or on any of the waters of the United States would be substantially impaired by the discharge;

(f) For the discharge of any radiological, chemical, or biological warfare agent or high-level radioactive waste;

(g) For any discharge inconsistent with a plan or plan amendment approved under section 208(b) of CWA;

(h) For any discharge to the territorial sea, the waters of the contiguous zone, or the oceans in the following circumstances:

(1) Before the promulgation of guidelines under section 403(c) of CWA (for determining degradation of the waters of the territorial seas, the contiguous zone, and the oceans) unless the Director determines permit issuance to be in the public interest; or

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(2) After promulgation of guidelines under section 403(c) of CWA, when insufficient information exists to make a reasonable judgment whether the discharge complies with them.

(i) To a new source or a new discharger, if the discharge from its construction or operation will cause or contribute to the violation of water quality standards. The owner or operator of a new source or new discharger proposing to discharge into a water segment which does not meet applicable water quality standards or is not expected to meet those standards even after the application of the effluent limitations required by sections 301(b)(1)(A) and 301(b)(1)(B) of CWA, and for which the State or interstate agency has performed a pollutants load allocation for the pollutant to be discharged, must demonstrate, before the close of the public comment period, that:

(1) There are sufficient remaining pollutant load allocations to allow for the discharge; and

(2) The existing dischargers into that segment are subject to compliance schedules designed to bring the segment into compliance with applicable water quality standards. The Director may waive the submission of information by the new source or new discharger required by paragraph (i) of this section if the Director determines that the Director already has adequate information to evaluate the request. An explanation of the development of limitations to meet the criteria of this paragraph (i)(2) is to be included in the fact sheet to the permit under § 124.56(b)(1) of this chapter.

[48 FR 14153, Apr. 1, 1983, as amended at 50 FR 6940, Feb. 19, 1985; 65 FR 30905, May 15, 2000]

§ 122.5 Effect of a permit.

(a) *Applicable to State programs, see § 123.25.* (1) Except for any toxic effluent standards and prohibitions imposed under section 307 of the CWA and "standards for sewage sludge use or disposal" under 405(d) of the CWA, compliance with a permit during its term constitutes compliance, for purposes of enforcement, with sections 301, 302, 306, 307, 318, 403, and 405 (a)–(b) of CWA. However, a permit may be modified, revoked and reissued, or terminated during its term for cause as set forth in §§ 122.62 and 122.64.

(2) Compliance with a permit condition which implements a particular "standard for sewage sludge use or disposal" shall be an affirmative defense in any enforcement action brought for a violation of that "standard for sewage sludge use or disposal" pursuant to sections 405(e) and 309 of the CWA.

(b) *Applicable to State programs, See § 123.25.* The issuance of a permit does not convey any property rights of any sort, or any exclusive privilege.

(c) The issuance of a permit does not authorize any injury to persons or property or invasion of other private rights, or any infringement of State or local law or regulations.

[48 FR 14153, Apr. 1, 1983, as amended at 54 FR 18782, May 2, 1989]

§ 122.6 Continuation of expiring permits.

(a) *EPA permits.* When EPA is the permit-issuing authority, the conditions of an expired permit continue in force under 5 U.S.C. 558(c) until the effective date of a new permit (see § 124.15) if:

(1) The permittee has submitted a timely application under § 122.21 which is a complete (under § 122.21(e)) application for a new permit; and

(2) The Regional Administrator, through no fault of the permittee does not issue a new permit with an effective date under § 124.15 on or before the expiration date of the previous permit (for example, when issuance is impracticable due to time or resource constraints).

(b) *Effect.* Permits continued under this section remain fully effective and enforceable.

(c) *Enforcement.* When the permittee is not in compliance with the conditions of the expiring or expired permit the Regional Administrator may choose to do any or all of the following:

(1) Initiate enforcement action based upon the permit which has been continued;

(2) Issue a notice of intent to deny the new permit under § 124.6. If the permit is denied, the owner or operator would then be required to cease the activities authorized by the continued

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permit or be subject to enforcement action for operating without a permit;

(3) Issue a new permit under part 124 with appropriate conditions; or

(4) Take other actions authorized by these regulations.

(d) *State continuation.* (1) An EPA-issued permit does not continue in force beyond its expiration date under Federal law if at that time a State is the permitting authority. States authorized to administer the NPDES program may continue either EPA or State-issued permits until the effective date of the new permits, if State law allows. Otherwise, the facility or activity is operating without a permit from the time of expiration of the old permit to the effective date of the State-issued new permit.

[48 FR 14153, Apr. 1, 1983, as amended at 50 FR 6940, Feb. 19, 1985]

§ 122.7 Confidentiality of information.

(a) In accordance with 40 CFR part 2, any information submitted to EPA pursuant to these regulations may be claimed as confidential by the submitter. Any such claim must be asserted at the time of submission in the manner prescribed on the application form or instructions or, in the case of other submissions, by stamping the words "confidential business information" on each page containing such information. If no claim is made at the time of submission, EPA may make the information available to the public without further notice. If a claim is asserted, the information will be treated in accordance with the procedures in 40 CFR part 2 (Public Information).

(b) *Applicable to State programs, see § 123.25.* Claims of confidentiality for the following information will be denied:

(1) The name and address of any permit applicant or permittee;

(2) Permit applications, permits, and effluent data.

(c) *Applicable to State programs, see § 123.25.* Information required by NPDES application forms provided by the Director under § 122.21 may not be claimed confidential. This includes information submitted on the forms themselves and any attachments used to supply information required by the forms.

Subpart B—Permit Application and Special NPDES Program Requirements

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

(a) *Duty to apply.* (1) Any person who discharges or proposes to discharge pollutants or who owns or operates a "sludge-only facility" whose sewage sludge use or disposal practice is regulated by part 503 of this chapter, and who does not have an effective permit, except persons covered by general permits under § 122.28, excluded under § 122.3, or a user of a privately owned treatment works unless the Director requires otherwise under § 122.44(m), must submit a complete application to the Director in accordance with this section and part 124 of this chapter. The requirements for concentrated animal feeding operations are described in § 122.23(d).

(2) *Application Forms:* (i) All applicants for EPA-issued permits must submit applications on EPA permit application forms. More than one application form may be required from a facility depending on the number and types of discharges or outfalls found there. Application forms may be obtained by contacting the EPA water resource center at (202) 260–7786 or Water Resource Center, U.S. EPA, Mail Code 4100, 1200 Pennsylvania Ave., NW., Washington, DC 20460 or at the EPA Internet site *www.epa.gov/owm/npdes.htm.* Applications for EPA-issued permits must be submitted as follows:

(A) All applicants, other than POTWs and TWTDS, must submit Form 1.

(B) Applicants for new and existing POTWs must submit the information contained in paragraph (j) of this section using Form 2A or other form provided by the director.

(C) Applicants for concentrated animal feeding operations or aquatic animal production facilities must submit Form 2B.

(D) Applicants for existing industrial facilities (including manufacturing facilities, commercial facilities, mining activities, and silvicultural activities), must submit Form 2C.

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(E) Applicants for new industrial facilities that discharge process wastewater must submit Form 2D.

(F) Applicants for new and existing industrial facilities that discharge only nonprocess wastewater must submit Form 2E.

(G) Applicants for new and existing facilities whose discharge is composed entirely of storm water associated with industrial activity must submit Form 2F, unless exempted by § 122.26(c)(1)(ii). If the discharge is composed of storm water and non-storm water, the applicant must also submit, Forms 2C, 2D, and/or 2E, as appropriate (in addition to Form 2F).

(H) Applicants for new and existing TWTDS, subject to paragraph (c)(2)(i) of this section must submit the application information required by paragraph (q) of this section, using Form 2S or other form provided by the director.

(ii) The application information required by paragraph (a)(2)(i) of this section may be electronically submitted if such method of submittal is approved by EPA or the Director.

(iii) Applicants can obtain copies of these forms by contacting the Water Management Divisions (or equivalent division which contains the NPDES permitting function) of the EPA Regional Offices. The Regional Offices' addresses can be found at § 1.7 of this chapter.

(iv) Applicants for State-issued permits must use State forms which must require at a minimum the information listed in the appropriate paragraphs of this section.

(b) *Who applies?* When a facility or activity is owned by one person but is operated by another person, it is the operator's duty to obtain a permit.

(c) *Time to apply.* (1) Any person proposing a new discharge, shall submit an application at least 180 days before the date on which the discharge is to commence, unless permission for a later date has been granted by the Director. Facilities proposing a new discharge of storm water associated with industrial activity shall submit an application 180 days before that facility commences industrial activity which may result in a discharge of storm water associated with that industrial activity. Facilities described under § 122.26(b)(14)(x) or (b)(15)(i) shall submit applications at least 90 days before the date on which construction is to commence. Different submittal dates may be required under the terms of applicable general permits. Persons proposing a new discharge are encouraged to submit their applications well in advance of the 90 or 180 day requirements to avoid delay. See also paragraph (k) of this section and § 122.26(c)(1)(i)(G) and (c)(1)(ii).

(2) *Permits under section 405(f) of CWA.* All TWTDS whose sewage sludge use or disposal practices are regulated by part 503 of this chapter must submit permit applications according to the applicable schedule in paragraphs (c)(2)(i) or (ii) of this section.

(i) A TWTDS with a currently effective NPDES permit must submit a permit application at the time of its next NPDES permit renewal application. Such information must be submitted in accordance with paragraph (d) of this section.

(ii) Any other TWTDS not addressed under paragraph (c)(2)(i) of this section must submit the information listed in paragraphs (c)(2)(ii)(A) through (E) of this section to the Director within 1 year after publication of a standard applicable to its sewage sludge use or disposal practice(s), using Form 2S or another form provided by the Director. The Director will determine when such TWTDS must submit a full permit application.

(A) The TWTDS's name, mailing address, location, and status as federal, State, private, public or other entity;

(B) The applicant's name, address, telephone number, and ownership status;

(C) A description of the sewage sludge use or disposal practices. Unless the sewage sludge meets the requirements of paragraph (q)(8)(iv) of this section, the description must include the name and address of any facility where sewage sludge is sent for treatment or disposal, and the location of any land application sites;

(D) Annual amount of sewage sludge generated, treated, used or disposed (estimated dry weight basis); and

(E) The most recent data the TWTDS may have on the quality of the sewage sludge.

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(iii) Notwithstanding paragraphs (c)(2)(i) or (ii) of this section, the Director may require permit applications from any TWTDS at any time if the Director determines that a permit is necessary to protect public health and the environment from any potential adverse effects that may occur from toxic pollutants in sewage sludge.

(iv) Any TWTDS that commences operations after promulgation of an applicable "standard for sewage sludge use or disposal" must submit an application to the Director at least 180 days prior to the date proposed for commencing operations.

(d) *Duty to reapply.* (1) Any POTW with a currently effective permit shall submit a new application at least 180 days before the expiration date of the existing permit, unless permission for a later date has been granted by the Director. (The Director shall not grant permission for applications to be submitted later than the expiration date of the existing permit.)

(2) All other permittees with currently effective permits shall submit a new application 180 days before the existing permit expires, except that:

(i) The Regional Administrator may grant permission to submit an application later than the deadline for submission otherwise applicable, but no later than the permit expiration date; and

(3) [Reserved]

(e) *Completeness.* (1) The Director shall not issue a permit before receiving a complete application for a permit except for NPDES general permits. An application for a permit is complete when the Director receives an application form and any supplemental information which are completed to his or her satisfaction. The completeness of any application for a permit shall be judged independently of the status of any other permit application or permit for the same facility or activity. For EPA administered NPDES programs, an application which is reviewed under § 124.3 of this chapter is complete when the Director receives either a complete application or the information listed in a notice of deficiency.

(2) A permit application shall not be considered complete if a permitting authority has waived application requirements under paragraphs (j) or (q) of this section and EPA has disapproved the waiver application. If a waiver request has been submitted to EPA more than 210 days prior to permit expiration and EPA has not disapproved the waiver application 181 days prior to permit expiration, the permit application lacking the information subject to the waiver application shall be considered complete.

(f) *Information requirements.* All applicants for NPDES permits, other than POTWs and other TWTDS, must provide the following information to the Director, using the application form provided by the Director. Additional information required of applicants is set forth in paragraphs (g) through (k) of this section.

(1) The activities conducted by the applicant which require it to obtain an NPDES permit.

(2) Name, mailing address, and location of the facility for which the application is submitted.

(3) Up to four SIC codes which best reflect the principal products or services provided by the facility.

(4) The operator's name, address, telephone number, ownership status, and status as Federal, State, private, public, or other entity.

(5) Whether the facility is located on Indian lands.

(6) A listing of all permits or construction approvals received or applied for under any of the following programs:

(i) Hazardous Waste Management program under RCRA.

(ii) UIC program under SDWA.

(iii) NPDES program under CWA.

(iv) Prevention of Significant Deterioration (PSD) program under the Clean Air Act.

(v) Nonattainment program under the Clean Air Act.

(vi) National Emission Standards for Hazardous Pollutants (NESHAPS) preconstruction approval under the Clean Air Act.

(vii) Ocean dumping permits under the Marine Protection Research and Sanctuaries Act.

(viii) Dredge or fill permits under section 404 of CWA.

(ix) Other relevant environmental permits, including State permits.

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(7) A topographic map (or other map if a topographic map is unavailable) extending one mile beyond the property boundaries of the source, depicting the facility and each of its intake and discharge structures; each of its hazardous waste treatment, storage, or disposal facilities; each well where fluids from the facility are injected underground; and those wells, springs, other surface water bodies, and drinking water wells listed in public records or otherwise known to the applicant in the map area.

(8) A brief description of the nature of the business.

(g) *Application requirements for existing manufacturing, commercial, mining, and silvicultural dischargers.* Existing manufacturing, commercial mining, and silvicultural dischargers applying for NPDES permits, except for those facilities subject to the requirements of § 122.21(h), shall provide the following information to the Director, using application forms provided by the Director.

(1) *Outfall location.* The latitude and longitude to the nearest 15 seconds and the name of the receiving water.

(2) *Line drawing.* A line drawing of the water flow through the facility with a water balance, showing operations contributing wastewater to the effluent and treatment units. Similar processes, operations, or production areas may be indicated as a single unit, labeled to correspond to the more detailed identification under paragraph (g)(3) of this section. The water balance must show approximate average flows at intake and discharge points and between units, including treatment units. If a water balance cannot be determined (for example, for certain mining activities), the applicant may provide instead a pictorial description of the nature and amount of any sources of water and any collection and treatment measures.

(3) *Average flows and treatment.* A narrative identification of each type of process, operation, or production area which contributes wastewater to the effluent for each outfall, including process wastewater, cooling water, and stormwater runoff; the average flow which each process contributes; and a description of the treatment the wastewater receives, including the ultimate disposal of any solid or fluid wastes other than by discharge. Processes, operations, or production areas may be described in general terms (for example, "dye-making reactor", "distillation tower"). For a privately owned treatment works, this information shall include the identity of each user of the treatment works. The average flow of point sources composed of storm water may be estimated. The basis for the rainfall event and the method of estimation must be indicated.

(4) *Intermittent flows.* If any of the discharges described in paragraph (g)(3) of this section are intermittent or seasonal, a description of the frequency, duration and flow rate of each discharge occurrence (except for stormwater runoff, spillage or leaks).

(5) *Maximum production.* If an effluent guideline promulgated under section 304 of CWA applies to the applicant and is expressed in terms of production (or other measure of operation), a reasonable measure of the applicant's actual production reported in the units used in the applicable effluent guideline. The reported measure must reflect the actual production of the facility as required by § 122.45(b)(2).

(6) *Improvements.* If the applicant is subject to any present requirements or compliance schedules for construction, upgrading or operation of waste treatment equipment, an identification of the abatement requirement, a description of the abatement project, and a listing of the required and projected final compliance dates.

(7) *Effluent characteristics.* (i) Information on the discharge of pollutants specified in this paragraph (g)(7) (except information on storm water discharges which is to be provided as specified in § 122.26). When "quantitative data" for a pollutant are required, the applicant must collect a sample of effluent and analyze it for the pollutant in accordance with analytical methods approved under Part 136 of this chapter unless use of another method is required for the pollutant under 40 CFR subchapters N or O. When no analytical method is approved under Part 136 or required under subchapters N or O, the applicant may use any suitable method

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but must provide a description of the method. When an applicant has two or more outfalls with substantially identical effluents, the Director may allow the applicant to test only one outfall and report that quantitative data as applying to the substantially identical outfall. The requirements in paragraphs (g)(7)(vi) and (vii) of this section state that an applicant must provide quantitative data for certain pollutants known or believed to be present do not apply to pollutants present in a discharge solely as the result of their presence in intake water; however, an applicant must report such pollutants as present. When paragraph (g)(7) of this section requires analysis of pH, temperature, cyanide, total phenols, residual chlorine, oil and grease, fecal coliform (including *E. coli*), and Enterococci (previously known as fecal streptococcus at § 122.26 (d)(2)(iii)(A)(3)), or volatile organics, grab samples must be collected for those pollutants. For all other pollutants, a 24-hour composite sample, using a minimum of four (4) grab samples, must be used unless specified otherwise at 40 CFR Part 136. However, a minimum of one grab sample may be taken for effluents from holding ponds or other impoundments with a retention period greater than 24 hours. In addition, for discharges other than storm water discharges, the Director may waive composite sampling for any outfall for which the applicant demonstrates that the use of an automatic sampler is infeasible and that the minimum of four (4) grab samples will be a representative sample of the effluent being discharged. Results of analyses of individual grab samples for any parameter may be averaged to obtain the daily average. Grab samples that are not required to be analyzed immediately (see Table II at 40 CFR 136.3 (e)) may be composited in the laboratory, provided that container, preservation, and holding time requirements are met (see Table II at 40 CFR 136.3 (e)) and that sample integrity is not compromised by compositing.

(ii) *Storm water discharges.* For storm water discharges, all samples shall be collected from the discharge resulting from a storm event that is greater than 0.1 inch and at least 72 hours from the previously measurable (greater than 0.1 inch rainfall) storm event. Where feasible, the variance in the duration of the event and the total rainfall of the event should not exceed 50 percent from the average or median rainfall event in that area. For all applicants, a flow-weighted composite shall be taken for either the entire discharge or for the first three hours of the discharge. The flow-weighted composite sample for a storm water discharge may be taken with a continuous sampler or as a combination of a minimum of three sample aliquots taken in each hour of discharge for the entire discharge or for the first three hours of the discharge, with each aliquot being separated by a minimum period of fifteen minutes (applicants submitting permit applications for storm water discharges under § 122.26(d) may collect flow-weighted composite samples using different protocols with respect to the time duration between the collection of sample aliquots, subject to the approval of the Director). However, a minimum of one grab sample may be taken for storm water discharges from holding ponds or other impoundments with a retention period greater than 24 hours. For a flow-weighted composite sample, only one analysis of the composite of aliquots is required. For storm water discharge samples taken from discharges associated with industrial activities, quantitative data must be reported for the grab sample taken during the first thirty minutes (or as soon thereafter as practicable) of the discharge for all pollutants specified in § 122.26(c)(1). For all storm water permit applicants taking flow-weighted composites, quantitative data must be reported for all pollutants specified in § 122.26 except pH, temperature, cyanide, total phenols, residual chlorine, oil and grease, fecal coliform, and fecal streptococcus. The Director may allow or establish appropriate site-specific sampling procedures or requirements, including sampling locations, the season in which the sampling takes place, the minimum duration between the previous measurable storm event and the storm event sampled, the minimum or maximum level of precipitation required for an appropriate storm event, the form of precipitation sampled

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(snow melt or rain fall), protocols for collecting samples under part 136 of this chapter, and additional time for submitting data on a case-by-case basis. An applicant is expected to ''know or have reason to believe'' that a pollutant is present in an effluent based on an evaluation of the expected use, production, or storage of the pollutant, or on any previous analyses for the pollutant. (For example, any pesticide manufactured by a facility may be expected to be present in contaminated storm water runoff from the facility.)

(iii) *Reporting requirements.* Every applicant must report quantitative data for every outfall for the following pollutants:

Biochemical Oxygen Demand (BOD5)
Chemical Oxygen Demand
Total Organic Carbon
Total Suspended Solids
Ammonia (as N)
Temperature (both winter and summer)
pH

(iv) The Director may waive the reporting requirements for individual point sources or for a particular industry category for one or more of the pollutants listed in paragraph (g)(7)(iii) of this section if the applicant has demonstrated that such a waiver is appropriate because information adequate to support issuance of a permit can be obtained with less stringent requirements.

(v) Each applicant with processes in one or more primary industry category (see appendix A of this part) contributing to a discharge must report quantitative data for the following pollutants in each outfall containing process wastewater:

(A) The organic toxic pollutants in the fractions designated in table I of appendix D of this part for the applicant's industrial category or categories unless the applicant qualifies as a small business under paragraph (g)(8) of this section. Table II of appendix D of this part lists the organic toxic pollutants in each fraction. The fractions result from the sample preparation required by the analytical procedure which uses gas chromatography/mass spectrometry. A determination that an applicant falls within a particular industrial category for the purposes of selecting fractions for testing is not conclusive as to the applicant's inclusion in that category for any other purposes. See Notes 2, 3, and 4 of this section.

(B) The pollutants listed in table III of appendix D of this part (the toxic metals, cyanide, and total phenols).

(vi)(A) Each applicant must indicate whether it knows or has reason to believe that any of the pollutants in table IV of appendix D of this part (certain conventional and nonconventional pollutants) is discharged from each outfall. If an applicable effluent limitations guideline either directly limits the pollutant or, by its express terms, indirectly limits the pollutant through limitations on an indicator, the applicant must report quantitative data. For every pollutant discharged which is not so limited in an effluent limitations guideline, the applicant must either report quantitative data or briefly describe the reasons the pollutant is expected to be discharged.

(B) Each applicant must indicate whether it knows or has reason to believe that any of the pollutants listed in table II or table III of appendix D of this part (the toxic pollutants and total phenols) for which quantitative data are not otherwise required under paragraph (g)(7)(v) of this section are discharged from each outfall. For every pollutant expected to be discharged in concentrations of 10 ppb or greater the applicant must report quantitative data. For acrolein, acrylonitrile, 2,4 dinitrophenol, and 2-methyl-4, 6 dinitrophenol, where any of these four pollutants are expected to be discharged in concentrations of 100 ppb or greater the applicant must report quantitative data. For every pollutant expected to be discharged in concentrations less than 10 ppb, or in the case of acrolein, acrylonitrile, 2,4 dinitrophenol, and 2-methyl-4, 6 dinitrophenol, in concentrations less than 100 ppb, the applicant must either submit quantitative data or briefly describe the reasons the pollutant is expected to be discharged. An applicant qualifying as a small business under paragraph (g)(8) of this section is not required to analyze for pollutants listed in table II of appendix D of this part (the organic toxic pollutants).

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(vii) Each applicant must indicate whether it knows or has reason to believe that any of the pollutants in table V of appendix D of this part (certain hazardous substances and asbestos) are discharged from each outfall. For every pollutant expected to be discharged, the applicant must briefly describe the reasons the pollutant is expected to be discharged, and report any quantitative data it has for any pollutant.

(viii) Each applicant must report qualitative data, generated using a screening procedure not calibrated with analytical standards, for 2,3,7,8-tetrachlorodibenzo-p-dioxin (TCDD) if it:

(A) Uses or manufactures 2,4,5-trichlorophenoxy acetic acid (2,4,5,-T); 2-(2,4,5-trichlorophenoxy) propanoic acid (Silvex, 2,4,5,-TP); 2-(2,4,5-trichlorophenoxy) ethyl, 2,2-dichloropropionate (Erbon); O,O-dimethyl O-(2,4,5-trichlorophenyl) phosphorothioate (Ronnel); 2,4,5-trichlorophenol (TCP); or hexachlorophene (HCP); or

(B) Knows or has reason to believe that TCDD is or may be present in an effluent.

(8) *Small business exemption.* An application which qualifies as a small business under one of the following criteria is exempt from the requirements in paragraph (g)(7)(v)(A) or (g)(7)(vi)(A) of this section to submit quantitative data for the pollutants listed in table II of appendix D of this part (the organic toxic pollutants):

(i) For coal mines, a probable total annual production of less than 100,000 tons per year.

(ii) For all other applicants, gross total annual sales averaging less than $100,000 per year (in second quarter 1980 dollars).

(9) *Used or manufactured toxics.* A listing of any toxic pollutant which the applicant currently uses or manufactures as an intermediate or final product or byproduct. The Director may waive or modify this requirement for any applicant if the applicant demonstrates that it would be unduly burdensome to identify each toxic pollutant and the Director has adequate information to issue the permit.

(10) [Reserved]

(11) *Biological toxicity tests.* An identification of any biological toxicity tests which the applicant knows or has reason to believe have been made within the last 3 years on any of the applicant's discharges or on a receiving water in relation to a discharge.

(12) *Contract analyses.* If a contract laboratory or consulting firm performed any of the analyses required by paragraph (g)(7) of this section, the identity of each laboratory or firm and the analyses performed.

(13) *Additional information.* In addition to the information reported on the application form, applicants shall provide to the Director, at his or her request, such other information as the Director may reasonably require to assess the discharges of the facility and to determine whether to issue an NPDES permit. The additional information may include additional quantitative data and bioassays to assess the relative toxicity of discharges to aquatic life and requirements to determine the cause of the toxicity.

(h) *Application requirements for manufacturing, commercial, mining and silvicultural facilities which discharge only non-process wastewater.* Except for stormwater discharges, all manufacturing, commercial, mining and silvicultural dischargers applying for NPDES permits which discharge only non-process wastewater not regulated by an effluent limitations guideline or new source performance standard shall provide the following information to the Director, using application forms provided by the Director:

(1) *Outfall location.* Outfall number, latitude and longitude to the nearest 15 seconds, and the name of the receiving water.

(2) *Discharge date* (for new dischargers). Date of expected commencement of discharge.

(3) *Type of waste.* An identification of the general type of waste discharged, or expected to be discharged upon commencement of operations, including sanitary wastes, restaurant or cafeteria wastes, or noncontact cooling water. An identification of cooling water additives (if any) that are used or expected to be used upon commencement of operations, along with their

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composition if existing composition is available.

(4) *Effluent characteristics.* (i) Quantitative data for the pollutants or parameters listed below, unless testing is waived by the Director. The quantitative data may be data collected over the past 365 days, if they remain representative of current operations, and must include maximum daily value, average daily value, and number of measurements taken. The applicant must collect and analyze samples in accordance with 40 CFR Part 136. When analysis of pH, temperature, residual chlorine, oil and grease, or fecal coliform (including *E. coli*), and Enterococci (previously known as fecal streptococcus) and volatile organics is required in paragraphs (h)(4)(i)(A) through (K) of this section, grab samples must be collected for those pollutants. For all other pollutants, a 24-hour composite sample, using a minimum of four (4) grab samples, must be used unless specified otherwise at 40 CFR Part 136. For a composite sample, only one analysis of the composite of aliquots is required. New dischargers must include estimates for the pollutants or parameters listed below instead of actual sampling data, along with the source of each estimate. All levels must be reported or estimated as concentration and as total mass, except for flow, pH, and temperature.

(A) Biochemical Oxygen Demand (BOD_5).

(B) Total Suspended Solids (TSS).

(C) Fecal Coliform (if believed present or if sanitary waste is or will be discharged).

(D) Total Residual Chlorine (if chlorine is used).

(E) Oil and Grease.

(F) Chemical Oxygen Demand (COD) (if non-contact cooling water is or will be discharged).

(G) Total Organic Carbon (TOC) (if non-contact cooling water is or will be discharged).

(H) Ammonia (as N).

(I) Discharge Flow.

(J) pH.

(K) Temperature (Winter and Summer).

(ii) The Director may waive the testing and reporting requirements for any of the pollutants or flow listed in paragraph (h)(4)(i) of this section if the applicant submits a request for such a waiver before or with his application which demonstrates that information adequate to support issuance of a permit can be obtained through less stringent requirements.

(iii) If the applicant is a new discharger, he must complete and submit Item IV of Form 2e (see § 122.21(h)(4)) by providing quantitative data in accordance with that section no later than two years after commencement of discharge. However, the applicant need not complete those portions of Item IV requiring tests which he has already performed and reported under the discharge monitoring requirements of his NPDES permit.

(iv) The requirements of parts i and iii of this section that an applicant must provide quantitative data or estimates of certain pollutants do not apply to pollutants present in a discharge solely as a result of their presence in intake water. However, an applicant must report such pollutants as present. Net credit may be provided for the presence of pollutants in intake water if the requirements of § 122.45(g) are met.

(5) *Flow.* A description of the frequency of flow and duration of any seasonal or intermittent discharge (except for stormwater runoff, leaks, or spills).

(6) *Treatment system.* A brief description of any system used or to be used.

(7) *Optional information.* Any additional information the applicant wishes to be considered, such as influent data for the purpose of obtaining "net" credits pursuant to § 122.45(g).

(8) *Certification.* Signature of certifying official under § 122.22.

(i) *Application requirements for new and existing concentrated animal feeding operations and aquatic animal production facilities.* New and existing concentrated animal feeding operations (defined in § 122.23) and concentrated aquatic animal production facilities (defined in § 122.24) shall provide the following information to the Director, using the application form provided by the Director:

(1) For concentrated animal feeding operations:

(i) The name of the owner or operator;

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(ii) The facility location and mailing addresses;

(iii) Latitude and longitude of the production area (entrance to production area);

(iv) A topographic map of the geographic area in which the CAFO is located showing the specific location of the production area, in lieu of the requirements of paragraph (f)(7) of this section;

(v) Specific information about the number and type of animals, whether in open confinement or housed under roof (beef cattle, broilers, layers, swine weighing 55 pounds or more, swine weighing less than 55 pounds, mature dairy cows, dairy heifers, veal calves, sheep and lambs, horses, ducks, turkeys, other);

(vi) The type of containment and storage (anaerobic lagoon, roofed storage shed, storage ponds, underfloor pits, above ground storage tanks, below ground storage tanks, concrete pad, impervious soil pad, other) and total capacity for manure, litter, and process wastewater storage(tons/gallons);

(vii) The total number of acres under control of the applicant available for land application of manure, litter, or process wastewater;

(viii) Estimated amounts of manure, litter, and process wastewater generated per year (tons/gallons);

(ix) Estimated amounts of manure, litter and process wastewater transferred to other persons per year (tons/gallons); and

(x) A nutrient management plan that at a minimum satisfies the requirements specified in § 122.42(e), including, for all CAFOs subject to 40 CFR part 412, subpart C or subpart D, the requirements of 40 CFR 412.4(c), as applicable.

(2) For concentrated aquatic animal production facilities:

(i) The maximum daily and average monthly flow from each outfall.

(ii) The number of ponds, raceways, and similar structures.

(iii) The name of the receiving water and the source of intake water.

(iv) For each species of aquatic animals, the total yearly and maximum harvestable weight.

(v) The calendar month of maximum feeding and the total mass of food fed during that month.

(j) *Application requirements for new and existing POTWs.* Unless otherwise indicated, all POTWs and other dischargers designated by the Director must provide, at a minimum, the information in this paragraph to the Director, using Form 2A or another application form provided by the Director. Permit applicants must submit all information available at the time of permit application. The information may be provided by referencing information previously submitted to the Director. The Director may waive any requirement of this paragraph if he or she has access to substantially identical information. The Director may also waive any requirement of this paragraph that is not of material concern for a specific permit, if approved by the Regional Administrator. The waiver request to the Regional Administrator must include the State's justification for the waiver. A Regional Administrator's disapproval of a State's proposed waiver does not constitute final Agency action, but does provide notice to the State and permit applicant(s) that EPA may object to any State-issued permit issued in the absence of the required information.

(1) *Basic application information.* All applicants must provide the following information:

(i) *Facility information.* Name, mailing address, and location of the facility for which the application is submitted;

(ii) *Applicant information.* Name, mailing address, and telephone number of the applicant, and indication as to whether the applicant is the facility's owner, operator, or both;

(iii) *Existing environmental permits.* Identification of all environmental permits or construction approvals received or applied for (including dates) under any of the following programs:

(A) Hazardous Waste Management program under the Resource Conservation and Recovery Act (RCRA), Subpart C;

(B) Underground Injection Control program under the Safe Drinking Water Act (SDWA);

(C) NPDES program under Clean Water Act (CWA);

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(D) Prevention of Significant Deterioration (PSD) program under the Clean Air Act;

(E) Nonattainment program under the Clean Air Act;

(F) National Emission Standards for Hazardous Air Pollutants (NESHAPS) preconstruction approval under the Clean Air Act;

(G) Ocean dumping permits under the Marine Protection Research and Sanctuaries Act;

(H) Dredge or fill permits under section 404 of the CWA; and

(I) Other relevant environmental permits, including State permits;

(iv) *Population.* The name and population of each municipal entity served by the facility, including unincorporated connector districts. Indicate whether each municipal entity owns or maintains the collection system and whether the collection system is separate sanitary or combined storm and sanitary, if known;

(v) *Indian country.* Information concerning whether the facility is located in Indian country and whether the facility discharges to a receiving stream that flows through Indian country;

(vi) *Flow rate.* The facility's design flow rate (the wastewater flow rate the plant was built to handle), annual average daily flow rate, and maximum daily flow rate for each of the previous 3 years;

(vii) *Collection system.* Identification of type(s) of collection system(s) used by the treatment works (i.e., separate sanitary sewers or combined storm and sanitary sewers) and an estimate of the percent of sewer line that each type comprises; and

(viii) *Outfalls and other discharge or disposal methods.* The following information for outfalls to waters of the United States and other discharge or disposal methods:

(A) For effluent discharges to waters of the United States, the total number and types of outfalls (e.g, treated effluent, combined sewer overflows, bypasses, constructed emergency overflows);

(B) For wastewater discharged to surface impoundments:

(*1*) The location of each surface impoundment;

(*2*) The average daily volume discharged to each surface impoundment; and

(*3*) Whether the discharge is continuous or intermittent;

(C) For wastewater applied to the land:

(*1*) The location of each land application site;

(*2*) The size of each land application site, in acres;

(*3*) The average daily volume applied to each land application site, in gallons per day; and

(*4*) Whether land application is continuous or intermittent;

(D) For effluent sent to another facility for treatment prior to discharge:

(*1*) The means by which the effluent is transported;

(*2*) The name, mailing address, contact person, and phone number of the organization transporting the discharge, if the transport is provided by a party other than the applicant;

(*3*) The name, mailing address, contact person, phone number, and NPDES permit number (if any) of the receiving facility; and

(*4*) The average daily flow rate from this facility into the receiving facility, in millions of gallons per day; and

(E) For wastewater disposed of in a manner not included in paragraphs (j)(1)(viii)(A) through (D) of this section (e.g., underground percolation, underground injection):

(*1*) A description of the disposal method, including the location and size of each disposal site, if applicable;

(*2*) The annual average daily volume disposed of by this method, in gallons per day; and

(*3*) Whether disposal through this method is continuous or intermittent;

(2) *Additional Information.* All applicants with a design flow greater than or equal to 0.1 mgd must provide the following information:

(i) *Inflow and infiltration.* The current average daily volume of inflow and infiltration, in gallons per day, and steps the facility is taking to minimize inflow and infiltration;

(ii) *Topographic map.* A topographic map (or other map if a topographic map is unavailable) extending at least one mile beyond property boundaries of

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the treatment plant, including all unit processes, and showing:

(A) Treatment plant area and unit processes;

(B) The major pipes or other structures through which wastewater enters the treatment plant and the pipes or other structures through which treated wastewater is discharged from the treatment plant. Include outfalls from bypass piping, if applicable;

(C) Each well where fluids from the treatment plant are injected underground;

(D) Wells, springs, and other surface water bodies listed in public records or otherwise known to the applicant within ¼ mile of the treatment works' property boundaries;

(E) Sewage sludge management facilities (including on-site treatment, storage, and disposal sites); and

(F) Location at which waste classified as hazardous under RCRA enters the treatment plant by truck, rail, or dedicated pipe;

(iii) *Process flow diagram or schematic.* (A) A diagram showing the processes of the treatment plant, including all bypass piping and all backup power sources or redundancy in the system. This includes a water balance showing all treatment units, including disinfection, and showing daily average flow rates at influent and discharge points, and approximate daily flow rates between treatment units; and

(B) A narrative description of the diagram; and

(iv) *Scheduled improvements, schedules of implementation.* The following information regarding scheduled improvements:

(A) The outfall number of each outfall affected;

(B) A narrative description of each required improvement;

(C) Scheduled or actual dates of completion for the following:

(*1*) Commencement of construction;

(*2*) Completion of construction;

(*3*) Commencement of discharge; and

(*4*) Attainment of operational level;

(D) A description of permits and clearances concerning other Federal and/or State requirements;

(3) *Information on effluent discharges.* Each applicant must provide the following information for each outfall, including bypass points, through which effluent is discharged, as applicable:

(i) *Description of outfall.* The following information about each outfall:

(A) Outfall number;

(B) State, county, and city or town in which outfall is located;

(C) Latitude and longitude, to the nearest second;

(D) Distance from shore and depth below surface;

(E) Average daily flow rate, in million gallons per day;

(F) The following information for each outfall with a seasonal or periodic discharge:

(*1*) Number of times per year the discharge occurs;

(*2*) Duration of each discharge;

(*3*) Flow of each discharge; and

(*4*) Months in which discharge occurs; and

(G) Whether the outfall is equipped with a diffuser and the type (e.g., high-rate) of diffuser used;

(ii) *Description of receiving waters.* The following information (if known) for each outfall through which effluent is discharged to waters of the United States:

(A) Name of receiving water;

(B) Name of watershed/river/stream system and United States Soil Conservation Service 14-digit watershed code;

(C) Name of State Management/River Basin and United States Geological Survey 8-digit hydrologic cataloging unit code; and

(D) Critical flow of receiving stream and total hardness of receiving stream at critical low flow (if applicable);

(iii) *Description of treatment.* The following information describing the treatment provided for discharges from each outfall to waters of the United States:

(A) The highest level of treatment (e.g., primary, equivalent to secondary, secondary, advanced, other) that is provided for the discharge for each outfall and:

(*1*) Design biochemical oxygen demand (BOD_5 or $CBOD_5$) removal (percent);

(*2*) Design suspended solids (SS) removal (percent); and, where applicable,

(*3*) Design phosphorus (P) removal (percent);

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(*4*) Design nitrogen (N) removal (percent); and

(*5*) Any other removals that an advanced treatment system is designed to achieve.

(B) A description of the type of disinfection used, and whether the treatment plant dechlorinates (if disinfection is accomplished through chlorination);

(4) *Effluent monitoring for specific parameters.* (i) As provided in paragraphs (j)(4)(ii) through (x) of this section, all applicants must submit to the Director effluent monitoring information for samples taken from each outfall through which effluent is discharged to waters of the United States, except for CSOs. The Director may allow applicants to submit sampling data for only one outfall on a case-by-case basis, where the applicant has two or more outfalls with substantially identical effluent. The Director may also allow applicants to composite samples from one or more outfalls that discharge into the same mixing zone;

(ii) All applicants must sample and analyze for the pollutants listed in Appendix J, Table 1A of this part;

(iii) All applicants with a design flow greater than or equal to 0.1 mgd must sample and analyze for the pollutants listed in Appendix J, Table 1 of this part. Facilities that do not use chlorine for disinfection, do not use chlorine elsewhere in the treatment process, and have no reasonable potential to discharge chlorine in their effluent may delete chlorine from Table 1;

(iv) The following applicants must sample and analyze for the pollutants listed in Appendix J, Table 2 of this part, and for any other pollutants for which the State or EPA have established water quality standards applicable to the receiving waters:

(A) All POTWs with a design flow rate equal to or greater than one million gallons per day;

(B) All POTWs with approved pretreatment programs or POTWs required to develop a pretreatment program;

(C) Other POTWs, as required by the Director;

(v) The Director should require sampling for additional pollutants, as appropriate, on a case-by-case basis;

(vi) Applicants must provide data from a minimum of three samples taken within four and one-half years prior to the date of the permit application. Samples must be representative of the seasonal variation in the discharge from each outfall. Existing data may be used, if available, in lieu of sampling done solely for the purpose of this application. The Director should require additional samples, as appropriate, on a case-by-case basis.

(vii) All existing data for pollutants specified in paragraphs (j)(4)(ii) through (v) of this section that is collected within four and one-half years of the application must be included in the pollutant data summary submitted by the applicant. If, however, the applicant samples for a specific pollutant on a monthly or more frequent basis, it is only necessary, for such pollutant, to summarize all data collected within one year of the application.

(viii) Applicants must collect samples of effluent and analyze such samples for pollutants in accordance with analytical methods approved under 40 CFR Part 136 unless an alternative is specified in the existing NPDES permit. When analysis of pH, temperature, cyanide, total phenols, residual chlorine, oil and grease, fecal coliform (including *E. coli*), or volatile organics is required in paragraphs (j)(4)(ii) through (iv) of this section, grab samples must be collected for those pollutants. For all other pollutants, 24-hour composite samples must be used. For a composite sample, only one analysis of the composite of aliquots is required.

(ix) The effluent monitoring data provided must include at least the following information for each parameter:

(A) Maximum daily discharge, expressed as concentration or mass, based upon actual sample values;

(B) Average daily discharge for all samples, expressed as concentration or mass, and the number of samples used to obtain this value;

(C) The analytical method used; and

(D) The threshold level (i.e., method detection limit, minimum level, or other designated method endpoints) for the analytical method used.

(x) Unless otherwise required by the Director, metals must be reported as total recoverable.

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(5) *Effluent monitoring for whole effluent toxicity.* (i) All applicants must provide an identification of any whole effluent toxicity tests conducted during the four and one-half years prior to the date of the application on any of the applicant's discharges or on any receiving water near the discharge.

(ii) As provided in paragraphs (j)(5)(iii)–(ix) of this section, the following applicants must submit to the Director the results of valid whole effluent toxicity tests for acute or chronic toxicity for samples taken from each outfall through which effluent is discharged to surface waters, except for combined sewer overflows:

(A) All POTWs with design flow rates greater than or equal to one million gallons per day;

(B) All POTWs with approved pretreatment programs or POTWs required to develop a pretreatment program;

(C) Other POTWs, as required by the Director, based on consideration of the following factors:

(*1*) The variability of the pollutants or pollutant parameters in the POTW effluent (based on chemical-specific information, the type of treatment plant, and types of industrial contributors);

(*2*) The ratio of effluent flow to receiving stream flow;

(*3*) Existing controls on point or nonpoint sources, including total maximum daily load calculations for the receiving stream segment and the relative contribution of the POTW;

(*4*) Receiving stream characteristics, including possible or known water quality impairment, and whether the POTW discharges to a coastal water, one of the Great Lakes, or a water designated as an outstanding natural resource water; or

(*5*) Other considerations (including, but not limited to, the history of toxic impacts and compliance problems at the POTW) that the Director determines could cause or contribute to adverse water quality impacts.

(iii) Where the POTW has two or more outfalls with substantially identical effluent discharging to the same receiving stream segment, the Director may allow applicants to submit whole effluent toxicity data for only one outfall on a case-by-case basis. The Director may also allow applicants to composite samples from one or more outfalls that discharge into the same mixing zone.

(iv) Each applicant required to perform whole effluent toxicity testing pursuant to paragraph (j)(5)(ii) of this section must provide:

(A) Results of a minimum of four quarterly tests for a year, from the year preceding the permit application; or

(B) Results from four tests performed at least annually in the four and one half year period prior to the application, provided the results show no appreciable toxicity using a safety factor determined by the permitting authority.

(v) Applicants must conduct tests with multiple species (no less than two species; e.g., fish, invertebrate, plant), and test for acute or chronic toxicity, depending on the range of receiving water dilution. EPA recommends that applicants conduct acute or chronic testing based on the following dilutions:

(A) Acute toxicity testing if the dilution of the effluent is greater than 1000:1 at the edge of the mixing zone;

(B) Acute or chronic toxicity testing if the dilution of the effluent is between 100:1 and 1000:1 at the edge of the mixing zone. Acute testing may be more appropriate at the higher end of this range (1000:1), and chronic testing may be more appropriate at the lower end of this range (100:1); and

(C) Chronic testing if the dilution of the effluent is less than 100:1 at the edge of the mixing zone.

(vi) Each applicant required to perform whole effluent toxicity testing pursuant to paragraph (j)(5)(ii) of this section must provide the number of chronic or acute whole effluent toxicity tests that have been conducted since the last permit reissuance.

(vii) Applicants must provide the results using the form provided by the Director, or test summaries if available and comprehensive, for each whole effluent toxicity test conducted pursuant to paragraph (j)(5)(ii) of this section for which such information has not been reported previously to the Director.

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(viii) Whole effluent toxicity testing conducted pursuant to paragraph (j)(5)(ii) of this section must be conducted using methods approved under 40 CFR part 136. West coast facilities in Washington, Oregon, California, Alaska, Hawaii, and the Pacific Territories are exempted from 40 CFR part 136 chronic methods and must use alternative guidance as directed by the permitting authority.

(ix) For whole effluent toxicity data submitted to the Director within four and one-half years prior to the date of the application, applicants must provide the dates on which the data were submitted and a summary of the results.

(x) Each POTW required to perform whole effluent toxicity testing pursuant to paragraph (j)(5)(ii) of this section must provide any information on the cause of toxicity and written details of any toxicity reduction evaluation conducted, if any whole effluent toxicity test conducted within the past four and one-half years revealed toxicity.

(6) *Industrial discharges.* Applicants must submit the following information about industrial discharges to the POTW:

(i) Number of significant industrial users (SIUs) and categorical industrial users (CIUs) discharging to the POTW; and

(ii) POTWs with one or more SIUs shall provide the following information for each SIU, as defined at 40 CFR 403.3(v), that discharges to the POTW:

(A) Name and mailing address;

(B) Description of all industrial processes that affect or contribute to the SIU's discharge;

(C) Principal products and raw materials of the SIU that affect or contribute to the SIU's discharge;

(D) Average daily volume of wastewater discharged, indicating the amount attributable to process flow and non-process flow;

(E) Whether the SIU is subject to local limits;

(F) Whether the SIU is subject to categorical standards, and if so, under which category(ies) and subcategory(ies); and

(G) Whether any problems at the POTW (e.g., upsets, pass through, interference) have been attributed to the SIU in the past four and one-half years.

(iii) The information required in paragraphs (j)(6)(i) and (ii) of this section may be waived by the Director for POTWs with pretreatment programs if the applicant has submitted either of the following that contain information substantially identical to that required in paragraphs (j)(6)(i) and (ii) of this section.

(A) An annual report submitted within one year of the application; or

(B) A pretreatment program;

(7) *Discharges from hazardous waste generators and from waste cleanup or remediation sites.* POTWs receiving Resource Conservation and Recovery Act (RCRA), Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA), or RCRA Corrective Action wastes or wastes generated at another type of cleanup or remediation site must provide the following information:

(i) If the POTW receives, or has been notified that it will receive, by truck, rail, or dedicated pipe any wastes that are regulated as RCRA hazardous wastes pursuant to 40 CFR part 261, the applicant must report the following:

(A) The method by which the waste is received (i.e., whether by truck, rail, or dedicated pipe); and

(B) The hazardous waste number and amount received annually of each hazardous waste;

(ii) If the POTW receives, or has been notified that it will receive, wastewaters that originate from remedial activities, including those undertaken pursuant to CERCLA and sections 3004(u) or 3008(h) of RCRA, the applicant must report the following:

(A) The identity and description of the site(s) or facility(ies) at which the wastewater originates;

(B) The identities of the wastewater's hazardous constituents, as listed in Appendix VIII of part 261 of this chapter; if known; and

(C) The extent of treatment, if any, the wastewater receives or will receive before entering the POTW;

(iii) Applicants are exempt from the requirements of paragraph (j)(7)(ii) of this section if they receive no more than fifteen kilograms per month of hazardous wastes, unless the wastes are

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acute hazardous wastes as specified in 40 CFR 261.30(d) and 261.33(e).

(8) *Combined sewer overflows.* Each applicant with combined sewer systems must provide the following information:

(i) *Combined sewer system information.* The following information regarding the combined sewer system:

(A) *System map.* A map indicating the location of the following:

(*1*) All CSO discharge points;

(*2*) Sensitive use areas potentially affected by CSOs (e.g., beaches, drinking water supplies, shellfish beds, sensitive aquatic ecosystems, and outstanding national resource waters); and

(*3*) Waters supporting threatened and endangered species potentially affected by CSOs; and

(B) *System diagram.* A diagram of the combined sewer collection system that includes the following information:

(*1*) The location of major sewer trunk lines, both combined and separate sanitary;

(*2*) The locations of points where separate sanitary sewers feed into the combined sewer system;

(*3*) In-line and off-line storage structures;

(*4*) The locations of flow-regulating devices; and

(*5*) The locations of pump stations;

(ii) *Information on CSO outfalls.* The following information for each CSO discharge point covered by the permit application:

(A) *Description of outfall.* The following information on each outfall:

(*1*) Outfall number;

(*2*) State, county, and city or town in which outfall is located;

(*3*) Latitude and longitude, to the nearest second; and

(*4*) Distance from shore and depth below surface;

(*5*) Whether the applicant monitored any of the following in the past year for this CSO:

(*i*) Rainfall;

(*ii*) CSO flow volume;

(*iii*) CSO pollutant concentrations;

(*iv*) Receiving water quality;

(*v*) CSO frequency; and

(*6*) The number of storm events monitored in the past year;

(B) *CSO events.* The following information about CSO overflows from each outfall:

(*1*) The number of events in the past year;

(*2*) The average duration per event, if available;

(*3*) The average volume per CSO event, if available; and

(*4*) The minimum rainfall that caused a CSO event, if available, in the last year;

(C) *Description of receiving waters.* The following information about receiving waters:

(*1*) Name of receiving water;

(*2*) Name of watershed/stream system and the United States Soil Conservation Service watershed (14-digit) code (if known); and

(*3*) Name of State Management/River Basin and the United States Geological Survey hydrologic cataloging unit (8-digit) code (if known); and

(D) *CSO operations.* A description of any known water quality impacts on the receiving water caused by the CSO (e.g., permanent or intermittent beach closings, permanent or intermittent shellfish bed closings, fish kills, fish advisories, other recreational loss, or exceedance of any applicable State water quality standard);

(9) *Contractors.* All applicants must provide the name, mailing address, telephone number, and responsibilities of all contractors responsible for any operational or maintenance aspects of the facility; and

(10) *Signature.* All applications must be signed by a certifying official in compliance with § 122.22.

(k) *Application requirements for new sources and new discharges.* New manufacturing, commercial, mining and silvicultural dischargers applying for NPDES permits (except for new discharges of facilities subject to the requirements of paragraph (h) of this section or new discharges of storm water associated with industrial activity which are subject to the requirements of § 122.26(c)(1) and this section (except as provided by § 122.26(c)(1)(ii)) shall provide the following information to the Director, using the application forms provided by the Director:

(1) *Expected outfall location.* The latitude and longitude to the nearest 15

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seconds and the name of the receiving water.

(2) *Discharge dates.* The expected date of commencement of discharge.

(3) *Flows, sources of pollution, and treatment technologies*—(i) *Expected treatment of wastewater.* Description of the treatment that the wastewater will receive, along with all operations contributing wastewater to the effluent, average flow contributed by each operation, and the ultimate disposal of any solid or liquid wastes not discharged.

(ii) *Line drawing.* A line drawing of the water flow through the facility with a water balance as described in § 122.21(g)(2).

(iii) *Intermittent flows.* If any of the expected discharges will be intermittent or seasonal, a description of the frequency, duration and maximum daily flow rate of each discharge occurrence (except for stormwater runoff, spillage, or leaks).

(4) *Production.* If a new source performance standard promulgated under section 306 of CWA or an effluent limitation guideline applies to the applicant and is expressed in terms of production (or other measure of operation), a reasonable measure of the applicant's expected actual production reported in the units used in the applicable effluent guideline or new source performance standard as required by § 122.45(b)(2) for each of the first three years. Alternative estimates may also be submitted if production is likely to vary.

(5) *Effluent characteristics.* The requirements in paragraphs (h)(4)(i), (ii), and (iii) of this section that an applicant must provide estimates of certain pollutants expected to be present do not apply to pollutants present in a discharge solely as a result of their presence in intake water; however, an applicant must report such pollutants as present. Net credits may be provided for the presence of pollutants in intake water if the requirements of § 122.45(g) are met. All levels (except for discharge flow, temperature, and pH) must be estimated as concentration and as total mass.

(i) Each applicant must report estimated daily maximum, daily average, and source of information for each outfall for the following pollutants or parameters. The Director may waive the reporting requirements for any of these pollutants and parameters if the applicant submits a request for such a waiver before or with his application which demonstrates that information adequate to support issuance of the permit can be obtained through less stringent reporting requirements.

(A) Biochemical Oxygen Demand (BOD).

(B) Chemical Oxygen Demand (COD).

(C) Total Organic Carbon (TOC).

(D) Total Suspended Solids (TSS).

(E) Flow.

(F) Ammonia (as N).

(G) Temperature (winter and summer).

(H) pH.

(ii) Each applicant must report estimated daily maximum, daily average, and source of information for each outfall for the following pollutants, if the applicant knows or has reason to believe they will be present or if they are limited by an effluent limitation guideline or new source performance standard either directly or indirectly through limitations on an indicator pollutant: all pollutants in table IV of appendix D of part 122 (certain conventional and nonconventional pollutants).

(iii) Each applicant must report estimated daily maximum, daily average and source of information for the following pollutants if he knows or has reason to believe that they will be present in the discharges from any outfall:

(A) The pollutants listed in table III of appendix D (the toxic metals, in the discharge from any outfall: Total cyanide, and total phenols);

(B) The organic toxic pollutants in table II of appendix D (except bis (chloromethyl) ether, dichlorofluoromethane and trichlorofluoromethane). This requirement is waived for applicants with expected gross sales of less than $100,000 per year for the next three years, and for coal mines with expected average production of less than 100,000 tons of coal per year.

(iv) The applicant is required to report that 2,3,7,8 Tetrachlorodibenzo-P-Dioxin (TCDD) may be discharged if he

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uses or manufactures one of the following compounds, or if he knows or has reason to believe that TCDD will or may be present in an effluent:

(A) 2,4,5-trichlorophenoxy acetic acid (2,4,5-T) (CAS #93–76–5);

(B) 2-(2,4,5-trichlorophenoxy) propanoic acid (Silvex, 2,4,5-TP) (CAS #93–72–1);

(C) 2-(2,4,5-trichlorophenoxy) ethyl 2,2-dichloropropionate (Erbon) (CAS #136–25–4);

(D) 0,0-dimethyl 0-(2,4,5-trichlorophenyl) phosphorothioate (Ronnel) (CAS #299–84–3);

(E) 2,4,5-trichlorophenol (TCP) (CAS #95–95–4); or

(F) Hexachlorophene (HCP) (CAS #70–30–4);

(v) Each applicant must report any pollutants listed in table V of appendix D (certain hazardous substances) if he believes they will be present in any outfall (no quantitative estimates are required unless they are already available).

(vi) No later than two years after the commencement of discharge from the proposed facility, the applicant is required to complete and submit Items V and VI of NPDES application Form 2c (see §122.21(g)). However, the applicant need not complete those portions of Item V requiring tests which he has already performed and reported under the discharge monitoring requirements of his NPDES permit.

(6) *Engineering Report.* Each applicant must report the existence of any technical evaluation concerning his wastewater treatment, along with the name and location of similar plants of which he has knowledge.

(7) *Other information.* Any optional information the permittee wishes to have considered.

(8) *Certification.* Signature of certifying official under §122.22.

(l) *Special provisions for applications from new sources.* (1) The owner or operator of any facility which may be a new source (as defined in §122.2) and which is located in a State without an approved NPDES program must comply with the provisions of this paragraph (l)(1).

(2)(i) Before beginning any on-site construction as defined in §122.29, the owner or operator of any facility which may be a new source must submit information to the Regional Administrator so that he or she can determine if the facility is a new source. The Regional Administrator may request any additional information needed to determine whether the facility is a new source.

(ii) The Regional Administrator shall make an initial determination whether the facility is a new source within 30 days of receiving all necessary information under paragraph (l)(2)(i) of this section.

(3) The Regional Administrator shall issue a public notice in accordance with §124.10 of this chapter of the new source determination under paragraph (l)(2) of this section. If the Regional Administrator has determined that the facility is a new source, the notice shall state that the applicant must comply with the environmental review requirements of 40 CFR 6.600 through 6.607.

(4) Any interested party may challenge the Regional Administrator's initial new source determination by requesting review of the determination under §124.19 of this chapter within 30 days of the public notice of the initial determination. If all interested parties agree, the Environmental Appeals Board may defer review until after a final permit decision is made, and consolidate review of the determination with any review of the permit decision.

(m) *Variance requests by non-POTWs.* A discharger which is not a publicly owned treatment works (POTW) may request a variance from otherwise applicable effluent limitations under any of the following statutory or regulatory provisions within the times specified in this paragraph:

(1) *Fundamentally different factors.* (i) A request for a variance based on the presence of "fundamentally different factors" from those on which the effluent limitations guideline was based shall be filed as follows:

(A) For a request from best practicable control technology currently available (BPT), by the close of the public comment period under §124.10.

(B) For a request from best available technology economically achievable

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(BAT) and/or best conventional pollutant control technology (BCT), by no later than:

(*1*) July 3, 1989, for a request based on an effluent limitation guideline promulgated before February 4, 1987, to the extent July 3, 1989 is not later than that provided under previously promulgated regulations; or

(*2*) 180 days after the date on which an effluent limitation guideline is published in the FEDERAL REGISTER for a request based on an effluent limitation guideline promulgated on or after February 4, 1987.

(ii) The request shall explain how the requirements of the applicable regulatory and/or statutory criteria have been met.

(2) *Non-conventional pollutants.* A request for a variance from the BAT requirements for CWA section 301(b)(2)(F) pollutants (commonly called "non-conventional" pollutants) pursuant to section 301(c) of CWA because of the economic capability of the owner or operator, or pursuant to section 301(g) of the CWA (provided however that a § 301(g) variance may only be requested for ammonia; chlorine; color; iron; total phenols (4AAP) (when determined by the Administrator to be a pollutant covered by section 301(b)(2)(F)) and any other pollutant which the Administrator lists under section 301(g)(4) of the CWA) must be made as follows:

(i) For those requests for a variance from an effluent limitation based upon an effluent limitation guideline by:

(A) Submitting an initial request to the Regional Administrator, as well as to the State Director if applicable, stating the name of the discharger, the permit number, the outfall number(s), the applicable effluent guideline, and whether the discharger is requesting a section 301(c) or section 301(g) modification or both. This request must have been filed not later than:

(*1*) September 25, 1978, for a pollutant which is controlled by a BAT effluent limitation guideline promulgated before December 27, 1977; or

(*2*) 270 days after promulgation of an applicable effluent limitation guideline for guidelines promulgated after December 27, 1977; and

(B) Submitting a completed request no later than the close of the public comment period under § 124.10 demonstrating that the requirements of § 124.13 and the applicable requirements of part 125 have been met. Notwithstanding this provision, the complete application for a request under section 301(g) shall be filed 180 days before EPA must make a decision (unless the Regional Division Director establishes a shorter or longer period).

(ii) For those requests for a variance from effluent limitations not based on effluent limitation guidelines, the request need only comply with paragraph (m)(2)(i)(B) of this section and need not be preceded by an initial request under paragraph (m)(2)(i)(A) of this section.

(3)–(4) [Reserved]

(5) *Water quality related effluent limitations.* A modification under section 302(b)(2) of requirements under section 302(a) for achieving water quality related effluent limitations may be requested no later than the close of the public comment period under § 124.10 on the permit from which the modification is sought.

(6) *Thermal discharges.* A variance under CWA section 316(a) for the thermal component of any discharge must be filed with a timely application for a permit under this section, except that if thermal effluent limitations are established under CWA section 402(a)(1) or are based on water quality standards the request for a variance may be filed by the close of the public comment period under § 124.10. A copy of the request as required under 40 CFR part 125, subpart H, shall be sent simultaneously to the appropriate State or interstate certifying agency as required under 40 CFR part 125. (See § 124.65 for special procedures for section 316(a) thermal variances.)

(n) *Variance requests by POTWs.* A discharger which is a publicly owned treatment works (POTW) may request a variance from otherwise applicable effluent limitations under any of the following statutory provisions as specified in this paragraph:

(1) *Discharges into marine waters.* A request for a modification under CWA section 301(h) of requirements of CWA section 301(b)(1)(B) for discharges into marine waters must be filed in accordance with the requirements of 40 CFR part 125, subpart G.

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(2) [Reserved]

(3) *Water quality based effluent limitation.* A modification under CWA section 302(b)(2) of the requirements under section 302(a) for achieving water quality based effluent limitations shall be requested no later than the close of the public comment period under § 124.10 on the permit from which the modification is sought.

(o) *Expedited variance procedures and time extensions.* (1) Notwithstanding the time requirements in paragraphs (m) and (n) of this section, the Director may notify a permit applicant before a draft permit is issued under § 124.6 that the draft permit will likely contain limitations which are eligible for variances. In the notice the Director may require the applicant as a condition of consideration of any potential variance request to submit a request explaining how the requirements of part 125 applicable to the variance have been met and may require its submission within a specified reasonable time after receipt of the notice. The notice may be sent before the permit application has been submitted. The draft or final permit may contain the alternative limitations which may become effective upon final grant of the variance.

(2) A discharger who cannot file a timely complete request required under paragraph (m)(2)(i)(B) or (m)(2)(ii) of this section may request an extension. The extension may be granted or denied at the discretion of the Director. Extensions shall be no more than 6 months in duration.

(p) *Recordkeeping.* Except for information required by paragraph (d)(3)(ii) of this section, which shall be retained for a period of at least five years from the date the application is signed (or longer as required by 40 CFR part 503), applicants shall keep records of all data used to complete permit applications and any supplemental information submitted under this section for a period of at least 3 years from the date the application is signed.

(q) *Sewage sludge management.* All TWTDS subject to paragraph (c)(2)(i) of this section must provide the information in this paragraph to the Director, using Form 2S or another application form approved by the Director. New applicants must submit all information available at the time of permit application. The information may be provided by referencing information previously submitted to the Director. The Director may waive any requirement of this paragraph if he or she has access to substantially identical information. The Director may also waive any requirement of this paragraph that is not of material concern for a specific permit, if approved by the Regional Administrator. The waiver request to the Regional Administrator must include the State's justification for the waiver. A Regional Administrator's disapproval of a State's proposed waiver does not constitute final Agency action, but does provide notice to the State and permit applicant(s) that EPA may object to any State-issued permit issued in the absence of the required information.

(1) *Facility information.* All applicants must submit the following information:

(i) The name, mailing address, and location of the TWTDS for which the application is submitted;

(ii) Whether the facility is a Class I Sludge Management Facility;

(iii) The design flow rate (in million gallons per day);

(iv) The total population served; and

(v) The TWTDS's status as Federal, State, private, public, or other entity;

(2) *Applicant information.* All applicants must submit the following information:

(i) The name, mailing address, and telephone number of the applicant; and

(ii) Indication whether the applicant is the owner, operator, or both;

(3) *Permit information.* All applicants must submit the facility's NPDES permit number, if applicable, and a listing of all other Federal, State, and local permits or construction approvals received or applied for under any of the following programs:

(i) Hazardous Waste Management program under the Resource Conservation and Recovery Act (RCRA);

(ii) UIC program under the Safe Drinking Water Act (SDWA);

(iii) NPDES program under the Clean Water Act (CWA);

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(iv) Prevention of Significant Deterioration (PSD) program under the Clean Air Act;

(v) Nonattainment program under the Clean Air Act;

(vi) National Emission Standards for Hazardous Air Pollutants (NESHAPS) preconstruction approval under the Clean Air Act;

(vii) Dredge or fill permits under section 404 of CWA;

(viii) Other relevant environmental permits, including State or local permits;

(4) *Indian country.* All applicants must identify any generation, treatment, storage, land application, or disposal of sewage sludge that occurs in Indian country;

(5) *Topographic map.* All applicants must submit a topographic map (or other map if a topographic map is unavailable) extending one mile beyond property boundaries of the facility and showing the following information:

(i) All sewage sludge management facilities, including on-site treatment, storage, and disposal sites; and

(ii) Wells, springs, and other surface water bodies that are within ¼ mile of the property boundaries and listed in public records or otherwise known to the applicant;

(6) *Sewage sludge handling.* All applicants must submit a line drawing and/or a narrative description that identifies all sewage sludge management practices employed during the term of the permit, including all units used for collecting, dewatering, storing, or treating sewage sludge, the destination(s) of all liquids and solids leaving each such unit, and all processes used for pathogen reduction and vector attraction reduction;

(7) *Sewage sludge quality.* The applicant must submit sewage sludge monitoring data for the pollutants for which limits in sewage sludge have been established in 40 CFR part 503 for the applicant's use or disposal practices on the date of permit application.

(i) The Director may require sampling for additional pollutants, as appropriate, on a case-by-case basis;

(ii) Applicants must provide data from a minimum of three samples taken within four and one-half years prior to the date of the permit application. Samples must be representative of the sewage sludge and should be taken at least one month apart. Existing data may be used in lieu of sampling done solely for the purpose of this application;

(iii) Applicants must collect and analyze samples in accordance with analytical methods approved under SW–846 unless an alternative has been specified in an existing sewage sludge permit;

(iv) The monitoring data provided must include at least the following information for each parameter:

(A) Average monthly concentration for all samples (mg/kg dry weight), based upon actual sample values;

(B) The analytical method used; and

(C) The method detection level.

(8) *Preparation of sewage sludge.* If the applicant is a "person who prepares" sewage sludge, as defined at 40 CFR 503.9(r), the applicant must provide the following information:

(i) If the applicant's facility generates sewage sludge, the total dry metric tons per 365-day period generated at the facility;

(ii) If the applicant's facility receives sewage sludge from another facility, the following information for each facility from which sewage sludge is received:

(A) The name, mailing address, and location of the other facility;

(B) The total dry metric tons per 365-day period received from the other facility; and

(C) A description of any treatment processes occurring at the other facility, including blending activities and treatment to reduce pathogens or vector attraction characteristics;

(iii) If the applicant's facility changes the quality of sewage sludge through blending, treatment, or other activities, the following information:

(A) Whether the Class A pathogen reduction requirements in 40 CFR 503.32(a) or the Class B pathogen reduction requirements in 40 CFR 503.32(b) are met, and a description of any treatment processes used to reduce pathogens in sewage sludge;

(B) Whether any of the vector attraction reduction options of 40 CFR 503.33(b)(1) through (b)(8) are met, and

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a description of any treatment processes used to reduce vector attraction properties in sewage sludge; and

(C) A description of any other blending, treatment, or other activities that change the quality of sewage sludge;

(iv) If sewage sludge from the applicant's facility meets the ceiling concentrations in 40 CFR 503.13(b)(1), the pollutant concentrations in §503.13(b)(3), the Class A pathogen requirements in §503.32(a), and one of the vector attraction reduction requirements in §503.33(b)(1) through (b)(8), and if the sewage sludge is applied to the land, the applicant must provide the total dry metric tons per 365-day period of sewage sludge subject to this paragraph that is applied to the land;

(v) If sewage sludge from the applicant's facility is sold or given away in a bag or other container for application to the land, and the sewage sludge is not subject to paragraph (q)(8)(iv) of this section, the applicant must provide the following information:

(A) The total dry metric tons per 365-day period of sewage sludge subject to this paragraph that is sold or given away in a bag or other container for application to the land; and

(B) A copy of all labels or notices that accompany the sewage sludge being sold or given away;

(vi) If sewage sludge from the applicant's facility is provided to another "person who prepares," as defined at 40 CFR 503.9(r), and the sewage sludge is not subject to paragraph (q)(8)(iv) of this section, the applicant must provide the following information for each facility receiving the sewage sludge:

(A) The name and mailing address of the receiving facility;

(B) The total dry metric tons per 365-day period of sewage sludge subject to this paragraph that the applicant provides to the receiving facility;

(C) A description of any treatment processes occurring at the receiving facility, including blending activities and treatment to reduce pathogens or vector attraction characteristic;

(D) A copy of the notice and necessary information that the applicant is required to provide the receiving facility under 40 CFR 503.12(g); and

(E) If the receiving facility places sewage sludge in bags or containers for sale or give-away to application to the land, a copy of any labels or notices that accompany the sewage sludge;

(9) *Land application of bulk sewage sludge.* If sewage sludge from the applicant's facility is applied to the land in bulk form, and is not subject to paragraphs (q)(8)(iv), (v), or (vi) of this section, the applicant must provide the following information:

(i) The total dry metric tons per 365-day period of sewage sludge subject to this paragraph that is applied to the land;

(ii) If any land application sites are located in States other than the State where the sewage sludge is prepared, a description of how the applicant will notify the permitting authority for the State(s) where the land application sites are located;

(iii) The following information for each land application site that has been identified at the time of permit application:

(A) The name (if any), and location for the land application site;

(B) The site's latitude and longitude to the nearest second, and method of determination;

(C) A topographic map (or other map if a topographic map is unavailable) that shows the site's location;

(D) The name, mailing address, and telephone number of the site owner, if different from the applicant;

(E) The name, mailing address, and telephone number of the person who applies sewage sludge to the site, if different from the applicant;

(F) Whether the site is agricultural land, forest, a public contact site, or a reclamation site, as such site types are defined under 40 CFR 503.11;

(G) The type of vegetation grown on the site, if known, and the nitrogen requirement for this vegetation;

(H) Whether either of the vector attraction reduction options of 40 CFR 503.33(b)(9) or (b)(10) is met at the site, and a description of any procedures employed at the time of use to reduce vector attraction properties in sewage sludge; and

(I) Other information that describes how the site will be managed, as specified by the permitting authority.

(iv) The following information for each land application site that has

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been identified at the time of permit application, if the applicant intends to apply bulk sewage sludge subject to the cumulative pollutant loading rates in 40 CFR 503.13(b)(2) to the site:

(A) Whether the applicant has contacted the permitting authority in the State where the bulk sewage sludge subject to §503.13(b)(2) will be applied, to ascertain whether bulk sewage sludge subject to §503.13(b)(2) has been applied to the site on or since July 20, 1993, and if so, the name of the permitting authority and the name and phone number of a contact person at the permitting authority;

(B) Identification of facilities other than the applicant's facility that have sent, or are sending, sewage sludge subject to the cumulative pollutant loading rates in §503.13(b)(2) to the site since July 20, 1993, if, based on the inquiry in paragraph (q)(iv)(A), bulk sewage sludge subject to cumulative pollutant loading rates in §503.13(b)(2) has been applied to the site since July 20, 1993;

(v) If not all land application sites have been identified at the time of permit application, the applicant must submit a land application plan that, at a minimum:

(A) Describes the geographical area covered by the plan;

(B) Identifies the site selection criteria;

(C) Describes how the site(s) will be managed;

(D) Provides for advance notice to the permit authority of specific land application sites and reasonable time for the permit authority to object prior to land application of the sewage sludge; and

(E) Provides for advance public notice of land application sites in the manner prescribed by State and local law. When State or local law does not require advance public notice, it must be provided in a manner reasonably calculated to apprize the general public of the planned land application.

(10) *Surface disposal.* If sewage sludge from the applicant's facility is placed on a surface disposal site, the applicant must provide the following information:

(i) The total dry metric tons of sewage sludge from the applicant's facility that is placed on surface disposal sites per 365-day period;

(ii) The following information for each surface disposal site receiving sewage sludge from the applicant's facility that the applicant does *not* own or operate:

(A) The site name or number, contact person, mailing address, and telephone number for the surface disposal site; and

(B) The total dry metric tons from the applicant's facility per 365-day period placed on the surface disposal site;

(iii) The following information for each active sewage sludge unit at each surface disposal site that the applicant owns or operates:

(A) The name or number and the location of the active sewage sludge unit;

(B) The unit's latitude and longitude to the nearest second, and method of determination;

(C) If not already provided, a topographic map (or other map if a topographic map is unavailable) that shows the unit's location;

(D) The total dry metric tons placed on the active sewage sludge unit per 365-day period;

(E) The total dry metric tons placed on the active sewage sludge unit over the life of the unit;

(F) A description of any liner for the active sewage sludge unit, including whether it has a maximum permeability of 1×10^{-7} cm/sec;

(G) A description of any leachate collection system for the active sewage sludge unit, including the method used for leachate disposal, and any Federal, State, and local permit number(s) for leachate disposal;

(H) If the active sewage sludge unit is less than 150 meters from the property line of the surface disposal site, the actual distance from the unit boundary to the site property line;

(I) The remaining capacity (dry metric tons) for the active sewage sludge unit;

(J) The date on which the active sewage sludge unit is expected to close, if such a date has been identified;

(K) The following information for any other facility that sends sewage sludge to the active sewage sludge unit:

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(*1*) The name, contact person, and mailing address of the facility; and

(*2*) Available information regarding the quality of the sewage sludge received from the facility, including any treatment at the facility to reduce pathogens or vector attraction characteristics;

(L) Whether any of the vector attraction reduction options of 40 CFR 503.33(b)(9) through (b)(11) is met at the active sewage sludge unit, and a description of any procedures employed at the time of disposal to reduce vector attraction properties in sewage sludge;

(M) The following information, as applicable to any ground-water monitoring occurring at the active sewage sludge unit:

(*1*) A description of any ground-water monitoring occurring at the active sewage sludge unit;

(*2*) Any available ground-water monitoring data, with a description of the well locations and approximate depth to ground water;

(*3*) A copy of any ground-water monitoring plan that has been prepared for the active sewage sludge unit;

(*4*) A copy of any certification that has been obtained from a qualified ground-water scientist that the aquifer has not been contaminated; and

(N) If site-specific pollutant limits are being sought for the sewage sludge placed on this active sewage sludge unit, information to support such a request;

(11) *Incineration*. If sewage sludge from the applicant's facility is fired in a sewage sludge incinerator, the applicant must provide the following information:

(i) The total dry metric tons of sewage sludge from the applicant's facility that is fired in sewage sludge incinerators per 365-day period;

(ii) The following information for each sewage sludge incinerator firing the applicant's sewage sludge that the applicant does *not* own or operate:

(A) The name and/or number, contact person, mailing address, and telephone number of the sewage sludge incinerator; and

(B) The total dry metric tons from the applicant's facility per 365-day period fired in the sewage sludge incinerator;

(iii) The following information for each sewage sludge incinerator that the applicant owns or operates:

(A) The name and/or number and the location of the sewage sludge incinerator;

(B) The incinerator's latitude and longitude to the nearest second, and method of determination;

(C) The total dry metric tons per 365-day period fired in the sewage sludge incinerator;

(D) Information, test data, and documentation of ongoing operating parameters indicating that compliance with the National Emission Standard for Beryllium in 40 CFR part 61 will be achieved;

(E) Information, test data, and documentation of ongoing operating parameters indicating that compliance with the National Emission Standard for Mercury in 40 CFR part 61 will be achieved;

(F) The dispersion factor for the sewage sludge incinerator, as well as modeling results and supporting documentation;

(G) The control efficiency for parameters regulated in 40 CFR 503.43, as well as performance test results and supporting documentation;

(H) Information used to calculate the risk specific concentration (RSC) for chromium, including the results of incinerator stack tests for hexavalent and total chromium concentrations, if the applicant is requesting a chromium limit based on a site-specific RSC value;

(I) Whether the applicant monitors total hydrocarbons (THC) or Carbon Monoxide (CO) in the exit gas for the sewage sludge incinerator;

(J) The type of sewage sludge incinerator;

(K) The maximum performance test combustion temperature, as obtained during the performance test of the sewage sludge incinerator to determine pollutant control efficiencies;

(L) The following information on the sewage sludge feed rate used during the performance test:

(*1*) Sewage sludge feed rate in dry metric tons per day;

(*2*) Identification of whether the feed rate submitted is average use or maximum design; and

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(*3*) A description of how the feed rate was calculated;

(M) The incinerator stack height in meters for each stack, including identification of whether actual or creditable stack height was used;

(N) The operating parameters for the sewage sludge incinerator air pollution control device(s), as obtained during the performance test of the sewage sludge incinerator to determine pollutant control efficiencies;

(O) Identification of the monitoring equipment in place, including (but not limited to) equipment to monitor the following:

(*1*) Total hydrocarbons or Carbon Monoxide;

(*2*) Percent oxygen;

(*3*) Percent moisture; and

(*4*) Combustion temperature; and

(P) A list of all air pollution control equipment used with this sewage sludge incinerator;

(12) *Disposal in a municipal solid waste landfill.* If sewage sludge from the applicant's facility is sent to a municipal solid waste landfill (MSWLF), the applicant must provide the following information for each MSWLF to which sewage sludge is sent:

(i) The name, contact person, mailing address, location, and all applicable permit numbers of the MSWLF;

(ii) The total dry metric tons per 365-day period sent from this facility to the MSWLF;

(iii) A determination of whether the sewage sludge meets applicable requirements for disposal of sewage sludge in a MSWLF, including the results of the paint filter liquids test and any additional requirements that apply on a site-specific basis; and

(iv) Information, if known, indicating whether the MSWLF complies with criteria set forth in 40 CFR part 258;

(13) *Contractors.* All applicants must provide the name, mailing address, telephone number, and responsibilities of all contractors responsible for any operational or maintenance aspects of the facility related to sewage sludge generation, treatment, use, or disposal;

(14) *Other information.* At the request of the permitting authority, the applicant must provide any other information necessary to determine the appropriate standards for permitting under 40 CFR part 503, and must provide any other information necessary to assess the sewage sludge use and disposal practices, determine whether to issue a permit, or identify appropriate permit requirements; and

(15) *Signature.* All applications must be signed by a certifying official in compliance with § 122.22.

[Note 1: At 46 FR 2046, Jan. 8, 1981, the Environmental Protection Agency suspended until further notice § 122.21(g)(7)(v)(A) and the corresponding portions of Item V-C of the NPDES application Form 2C as they apply to coal mines. This suspension continues in effect.]

[Note 2: At 46 FR 22585, Apr. 20, 1981, the Environmental Protection Agency suspended until further notice § 122.21(g)(7)(v)(A) and the corresponding portions of Item V-C of the NPDES application Form 2C as they apply to:

a. Testing and reporting for all four organic fractions in the Greige Mills Subcategory of the Textile Mills industry (subpart C—Low water use processing of 40 CFR part 410), and testing and reporting for the pesticide fraction in all other subcategories of this industrial category.

b. Testing and reporting for the volatile, base/neutral and pesticide fractions in the Base and Precious Metals Subcategory of the Ore Mining and Dressing industry (subpart B of 40 CFR part 440), and testing and reporting for all four fractions in all other subcategories of this industrial category.

c. Testing and reporting for all four GC/MS fractions in the Porcelain Enameling industry.

This revision continues that suspension.][1]

[Note 3: At 46 FR 35090, July 1, 1981, the Environmental Protection Agency suspended until further notice § 122.21(g)(7)(v)(A) and the corresponding portions of Item V-C of the NPDES application Form 2C as they apply to:

a. Testing and reporting for the pesticide fraction in the Tall Oil Rosin Subcategory (subpart D) and Rosin-Based Derivatives Subcategory (subpart F) of the Gum and Wood Chemicals industry (40 CFR part 454), and testing and reporting for the pesticide and base-neutral fractions in all other subcategories of this industrial category.

b. Testing and reporting for the pesticide fraction in the Leather Tanning and Finishing, Paint and Ink Formulation, and Photographic Supplies industrial categories.

c. Testing and reporting for the acid, base/neutral and pesticide fractions in the Petroleum Refining industrial category.

d. Testing and reporting for the pesticide fraction in the Papergrade Sulfite subcategories (subparts J and U) of the Pulp and Paper industry (40 CFR part 430); testing and

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reporting for the base/neutral and pesticide fractions in the following subcategories: Deink (subpart Q), Dissolving Kraft (subpart F), and Paperboard from Waste Paper (subpart E); testing and reporting for the volatile, base/neutral and pesticide fractions in the following subcategories: BCT Bleached Kraft (subpart H), Semi-Chemical (subparts B and C), and Nonintegrated-Fine Papers (subpart R); and testing and reporting for the acid, base/neutral, and pesticide fractions in the following subcategories: Fine Bleached Kraft (subpart I), Dissolving Sulfite Pulp (subpart K), Groundwood-Fine Papers (subpart O), Market Bleached Kraft (subpart G), Tissue from Wastepaper (subpart T), and Nonintegrated-Tissue Papers (subpart S).

e. Testing and reporting for the base/neutral fraction in the Once-Through Cooling Water, Fly Ash and Bottom Ash Transport Water process wastestreams of the Steam Electric Power Plant industrial category.

This revision continues that suspension.][1]

(r) *Application requirements for facilities with cooling water intake structures*—(1)(i) *New facilities with new or modified cooling water intake structures.* New facilities (other than offshore oil and gas extraction facilities) with cooling water intake structures as defined in part 125, subpart I, of this chapter must submit to the Director for review the information required under paragraphs (r)(2) (except (r)(2)(iv)), (3), and (4) of this section and §125.86 of this chapter as part of their application. New offshore oil and gas extraction facilities with cooling water intake structures as defined in part 125, subpart N, of this chapter that are fixed facilities must submit to the Director for review the information required under paragraphs (r)(2) (except (r)(2)(iv)), (3), and (4) of this section and §125.136 of this chapter as part of their application. New offshore oil and gas extraction facilities that are *not* fixed facilities must submit to the Director for review only the information required under paragraphs (r)(2)(iv), (r)(3) (except (r)(3)(ii)), and §125.136 of this chapter as part of their application. Requests for alternative requirements under §125.85 or §125.135 of this chapter must be submitted with your permit application.

(ii) *Phase II existing facilities.* Phase II existing facilities as defined in part 125, subpart J, of this chapter must submit to the Director for review the information required under paragraphs (r)(2), (3), and (5) of this section and all applicable provisions of §125.95 of this chapter as part of their application except for the Proposal for Information Collection which must be provided in accordance with §125.95(b)(1).

(2) *Source water physical data.* These include:

(i) A narrative description and scaled drawings showing the physical configuration of all source water bodies used by your facility, including areal dimensions, depths, salinity and temperature regimes, and other documentation that supports your determination of the water body type where each cooling water intake structure is located;

(ii) Identification and characterization of the source waterbody's hydrological and geomorphological features, as well as the methods you used to conduct any physical studies to determine your intake's area of influence within the waterbody and the results of such studies;

(iii) Locational maps; and

(iv) For new offshore oil and gas facilities that are not fixed facilities, a narrative description and/or locational maps providing information on predicted locations within the waterbody during the permit term in sufficient detail for the Director to determine the appropriateness of additional impingement requirements under §125.134(b)(4).

(3) *Cooling water intake structure data.* These include:

(i) A narrative description of the configuration of each of your cooling water intake structures and where it is located in the water body and in the water column;

(ii) Latitude and longitude in degrees, minutes, and seconds for each of your cooling water intake structures;

(iii) A narrative description of the operation of each of your cooling water intake structures, including design intake flows, daily hours of operation, number of days of the year in operation and seasonal changes, if applicable;

(iv) A flow distribution and water balance diagram that includes all sources of water to the facility, recirculating flows, and discharges; and

(v) Engineering drawings of the cooling water intake structure.

[1] EDITORIAL NOTE: The words "This revision" refer to the document published at 48 FR 14153, Apr. 1, 1983.

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(4) Source water baseline biological characterization data. This information is required to characterize the biological community in the vicinity of the cooling water intake structure and to characterize the operation of the cooling water intake structures. The Director may also use this information in subsequent permit renewal proceedings to determine if your Design and Construction Technology Plan as required in § 125.86(b)(4) or § 125.136(b)(3) of this chapter should be revised. This supporting information must include existing data (if they are available). However, you may supplement the data using newly conducted field studies if you choose to do so. The information you submit must include:

(i) A list of the data in paragraphs (r)(4)(ii) through (vi) of this section that are not available and efforts made to identify sources of the data;

(ii) A list of species (or relevant taxa) for all life stages and their relative abundance in the vicinity of the cooling water intake structure;

(iii) Identification of the species and life stages that would be most susceptible to impingement and entrainment. Species evaluated should include the forage base as well as those most important in terms of significance to commercial and recreational fisheries;

(iv) Identification and evaluation of the primary period of reproduction, larval recruitment, and period of peak abundance for relevant taxa;

(v) Data representative of the seasonal and daily activities (e.g., feeding and water column migration) of biological organisms in the vicinity of the cooling water intake structure;

(vi) Identification of all threatened, endangered, and other protected species that might be susceptible to impingement and entrainment at your cooling water intake structures;

(vii) Documentation of any public participation or consultation with Federal or State agencies undertaken in development of the plan; and

(viii) If you supplement the information requested in paragraph (r)(4)(i) of this section with data collected using field studies, supporting documentation for the Source Water Baseline Biological Characterization must include a description of all methods and quality assurance procedures for sampling, and data analysis including a description of the study area; taxonomic identification of sampled and evaluated biological assemblages (including all life stages of fish and shellfish); and sampling and data analysis methods. The sampling and/or data analysis methods you use must be appropriate for a quantitative survey and based on consideration of methods used in other biological studies performed within the same source water body. The study area should include, at a minimum, the area of influence of the cooling water intake structure.

(5) *Cooling water system data.* Phase II existing facilities as defined in part 125, subpart J of this chapter must provide the following information for each cooling water intake structure they use:

(i) A narrative description of the operation of the cooling water system, its relationship to cooling water intake structures, the proportion of the design intake flow that is used in the system, the number of days of the year the cooling water system is in operation and seasonal changes in the operation of the system, if applicable; and

(ii) Design and engineering calculations prepared by a qualified professional and supporting data to support the description required by paragraph (r)(5)(i) of this section.

[48 FR 14153, Apr. 1, 1983]

EDITORIAL NOTE: For FEDERAL REGISTER citations affecting § 122.21, see the List of CFR Sections Affected, which appears in the Finding Aids section of the printed volume and on GPO Access.

EFFECTIVE DATE NOTE: At 72 FR 37109, July 9, 2007, § 122.21(r)(1)(ii) and (r)(5) were suspended.

§ 122.22 Signatories to permit applications and reports (applicable to State programs, see § 123.25).

(a) *Applications.* All permit applications shall be signed as follows:

(1) *For a corporation.* By a responsible corporate officer. For the purpose of this section, a responsible corporate officer means: (i) A president, secretary, treasurer, or vice-president of the corporation in charge of a principal business function, or any other person who perfoms similar policy- or decision-

Zinc
Cyanide
Total phenolic compounds
Volatile organic compounds
Acrolein
Acrylonitrile
Benzene
Bromoform
Carbon tetrachloride
Chlorobenzene
Chlorodibromomethane
Chloroethane
2-chloroethylvinyl ether
Chloroform
Dichlorobromomethane
1,1-dichloroethane
1,2-dichloroethane
Trans-1,2-dichloroethylene
1,1-dichloroethylene
1,2-dichloropropane
1,3-dichloropropylene
Ethylbenzene
Methyl bromide
Methyl chloride
Methylene chloride
1,1,2,2-tetrachloroethane
Tetrachloroethylene
Toluene
1,1,1-trichloroethane
1,1,2-trichloroethane
Trichloroethylene
Vinyl chloride
Acid-extractable compounds
P-chloro-m-creso
2-chlorophenol
2,4-dichlorophenol
2,4-dimethylphenol
4,6-dinitro-o-cresol
2,4-dinitrophenol
2-nitrophenol
4-nitrophenol
Pentachlorophenol
Phenol
2,4,6-trichlorophenol
Base-neutral compounds
Acenaphthene
Acenaphthylene
Anthracene
Benzidine
Benzo(a)anthracene
Benzo(a)pyrene
3,4 benzofluoranthene
Benzo(ghi)perylene
Benzo(k)fluoranthene
Bis (2-chloroethoxy) methane
Bis (2-chloroethyl) ether
Bis (2-chloroisopropyl) ether
Bis (2-ethylhexyl) phthalate
4-bromophenyl phenyl ether
Butyl benzyl phthalate
2-chloronaphthalene
4-chlorophenyl phenyl ether
Chrysene
Di-n-butyl phthalate
Di-n-octyl phthalate
Dibenzo(a,h)anthracene
1,2-dichlorobenzene
1,3-dichlorobenzene
1,4-dichlorobenzene
3,3-dichlorobenzidine
Diethyl phthalate
Dimethyl phthalate
2,4-dinitrotoluene
2,6-dinitrotoluene
1,2-diphenylhydrazine
Fluoranthene
Fluorene
Hexachlorobenzene
Hexachlorobutadiene
Hexachlorocyclo-pentadiene
Hexachloroethane
Indeno(1,2,3-cd)pyrene
Isophorone
Naphthalene
Nitrobenzene
N-nitrosodi-n-propylamine
N-nitrosodimethylamine
N-nitrosodiphenylamine
Phenanthrene
Pyrene
1,2,4,-trichlorobenzene

[65 FR 42469, Aug. 4, 2000]

PART 123—STATE PROGRAM REQUIREMENTS

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

SOURCE: 48 FR 14178, Apr. 1, 1983, unless otherwise noted.

Subpart A—General

§ 123.1 Purpose and scope.

(a) This part specifies the procedures EPA will follow in approving, revising, and withdrawing State programs and the requirements State programs must meet to be approved by the Administrator under sections 318, 402, and 405(a) (National Pollutant Discharge Elimination System—NPDES) of the CWA. This part also specifies the procedures EPA will follow in approving, revising, and withdrawing State programs under section 405(f) (sludge management programs) of the CWA. The requirements that a State sewage sludge management program must meet for approval by the Administrator under section 405(f) are set out at 40 CFR part 501.

(b) These regulations are promulgated under the authority of sections 304(i), 101(e), 405, and 518(e) of the CWA, and implement the requirements of those sections.

(c) The Administrator will approve State programs which conform to the applicable requirements of this part. A State NPDES program will not be approved by the Administrator under section 402 of CWA unless it has authority to control the discharges specified in sections 318 and 405(a) of CWA. Permit programs under sections 318 and 405(a) will not be approved independent of a section 402 program.

(d)(1) Upon approval of a State program, the Administrator shall suspend the issuance of Federal permits for those activities subject to the approved State program. After program approval EPA shall retain jurisdiction over any permits (including general permits) which it has issued unless arrangements have been made with the State in the Memorandum of Agreement for the State to assume responsibility for these permits. Retention of jurisdiction shall include the processing of any permit appeals, modification requests, or variance requests; the conduct of inspections, and the receipt and review of self-monitoring reports. If any permit appeal, modification request or variance request is not finally resolved when the federally issued permit expires, EPA may, with the consent of the State, retain jurisdiction until the matter is resolved.

(2) The procedures outlined in the preceding paragraph (d)(1) of this section for suspension of permitting authority and transfer of existing permits will also apply when EPA approves an Indian Tribe's application to operate a State program and a State was the authorized permitting authority under § 123.23(b) for activities within the scope of the newly approved program. The authorized State will retain jurisdiction over its existing permits as described in paragraph (d)(1) of this section absent a different arrangement stated in the Memorandum of Agreement executed between EPA and the Tribe.

(e) Upon submission of a complete program, EPA will conduct a public hearing, if interest is shown, and determine whether to approve or disapprove the program taking into consideration the requirements of this part, the CWA and any comments received.

(f) Any State program approved by the Administrator shall at all times be conducted in accordance with the requirements of this part.

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(3) Any written materials submitted at such a hearing;

(4) The response to comments required by § 124.17 and any new material placed in the record under that section;

(5) For NPDES new source permits only, final environmental impact statement and any supplement to the final EIS;

(6) Other documents contained in the supporting file for the permit; and

(7) The final permit.

(c) The additional documents required under paragraph (b) of this section should be added to the record as soon as possible after their receipt or publication by the Agency. The record shall be complete on the date the final permit is issued.

(d) This section applies to all final RCRA, UIC, PSD, and NPDES permits when the draft permit was subject to the administrative record requirements of § 124.9 and to all NPDES permits when the draft permit was included in a public notice after October 12, 1979.

(e) Material readily available at the issuing Regional Office, or published materials which are generally available and which are included in the administrative record under the standards of this section or of § 124.17 (''Response to comments''), need not be physically included in the same file as the rest of the record as long as it is specifically referred to in the statement of basis or fact sheet or in the response to comments.

§ 124.19 Appeal of RCRA, UIC, NPDES, and PSD Permits.

(a) Within 30 days after a RCRA, UIC, NPDES, or PSD final permit decision (or a decision under 270.29 of this chapter to deny a permit for the active life of a RCRA hazardous waste management facility or unit) has been issued under § 124.15 of this part, any person who filed comments on that draft permit or participated in the public hearing may petition the Environmental Appeals Board to review any condition of the permit decision. Persons affected by an NPDES general permit may not file a petition under this section or otherwise challenge the conditions of the general permit in further Agency proceedings. They may, instead, either challenge the general permit in court, or apply for an individual NPDES permit under § 122.21 as authorized in § 122.28 and then petition the Board for review as provided by this section. As provided in § 122.28(b)(3), any interested person may also petition the Director to require an individual NPDES permit for any discharger eligible for authorization to discharge under an NPDES general permit. Any person who failed to file comments or failed to participate in the public hearing on the draft permit may petition for administrative review only to the extent of the changes from the draft to the final permit decision. The 30-day period within which a person may request review under this section begins with the service of notice of the Regional Administrator's action unless a later date is specified in that notice. The petition shall include a statement of the reasons supporting that review, including a demonstration that any issues being raised were raised during the public comment period (including any public hearing) to the extent required by these regulations and when appropriate, a showing that the condition in question is based on:

(1) A finding of fact or conclusion of law which is clearly erroneous, or

(2) An exercise of discretion or an important policy consideration which the Environmental Appeals Board should, in its discretion, review.

(b) The Environmental Appeals Board may also decide on its own initiative to review any condition of any RCRA, UIC, NPDES, or PSD permit decision issued under this part for which review is available under paragraph (a) of this section. The Environmental Appeals Board must act under this paragraph within 30 days of the service date of notice of the Regional Administrator's action.

(c) Within a reasonable time following the filing of the petition for review, the Environmental Appeals Board shall issue an order granting or denying the petition for review. To the extent review is denied, the conditions of the final permit decision become final agency action. Public notice of any grant of review by the Environmental Appeals Board under paragraph (a) or (b) of this section shall be given

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which may include the administration of programs and services authorized by the Indian Self-Determination and Education Assistance Act (25 U.S.C. 450 *et seq.*), the Indian Mineral Development Act (25 U.S.C. 2101 *et seq.*), or the Indian Sanitation Facility Construction Activity Act (42 U.S.C. 2004a);

(ii) A list of existing environmental or public health programs administered by the Tribal governing body and copies of related Tribal laws, policies, and regulations;

(iii) A description of the entity (or entities) which exercise the executive, legislative, and judicial functions of the Tribal government;

(iv) A description of the existing, or proposed, agency of the Indian Tribe which will assume primary responsibility for establishing, reviewing, implementing and revising water quality standards;

(v) A description of the technical and administrative capabilities of the staff to administer and manage an effective water quality standards program or a plan which proposes how the Tribe will acquire additional administrative and technical expertise. The plan must address how the Tribe will obtain the funds to acquire the administrative and technical expertise.

(5) Additional documentation required by the Regional Administrator which, in the judgment of the Regional Administrator, is necessary to support a Tribal application.

(6) Where the Tribe has previously qualified for eligibility or "treatment as a state" under a Clean Water Act or Safe Drinking Water Act program, the Tribe need only provide the required information which has not been submitted in a previous application.

(c) Procedure for processing an Indian Tribe's application.

(1) The Regional Administrator shall process an application of an Indian Tribe submitted pursuant to § 131.8(b) in a timely manner. He shall promptly notify the Indian Tribe of receipt of the application.

(2) Within 30 days after receipt of the Indian Tribe's application the Regional Administrator shall provide appropriate notice. Notice shall:

(i) Include information on the substance and basis of the Tribe's assertion of authority to regulate the quality of reservation waters; and

(ii) Be provided to all appropriate governmental entities.

(3) The Regional Administrator shall provide 30 days for comments to be submitted on the Tribal application. Comments shall be limited to the Tribe's assertion of authority.

(4) If a Tribe's asserted authority is subject to a competing or conflicting claim, the Regional Administrator, after due consideration, and in consideration of other comments received, shall determine whether the Tribe has adequately demonstrated that it meets the requirements of § 131.8(a)(3).

(5) Where the Regional Administrator determines that a Tribe meets the requirements of this section, he shall promptly provide written notification to the Indian Tribe that the Tribe is authorized to administer the Water Quality Standards program.

[56 FR 64895, Dec. 12, 1991, as amended at 59 FR 64344, Dec. 14, 1994]

Subpart B—Establishment of Water Quality Standards

§ 131.10 Designation of uses.

(a) Each State must specify appropriate water uses to be achieved and protected. The classification of the waters of the State must take into consideration the use and value of water for public water supplies, protection and propagation of fish, shellfish and wildlife, recreation in and on the water, agricultural, industrial, and other purposes including navigation. In no case shall a State adopt waste transport or waste assimilation as a designated use for any waters of the United States.

(b) In designating uses of a water body and the appropriate criteria for those uses, the State shall take into consideration the water quality standards of downstream waters and shall ensure that its water quality standards provide for the attainment and maintenance of the water quality standards of downstream waters.

(c) States may adopt sub-categories of a use and set the appropriate criteria to reflect varying needs of such sub-categories of uses, for instance, to

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differentiate between cold water and warm water fisheries.

(d) At a minimum, uses are deemed attainable if they can be achieved by the imposition of effluent limits required under sections 301(b) and 306 of the Act and cost-effective and reasonable best management practices for nonpoint source control.

(e) Prior to adding or removing any use, or establishing sub-categories of a use, the State shall provide notice and an opportunity for a public hearing under § 131.20(b) of this regulation.

(f) States may adopt seasonal uses as an alternative to reclassifying a water body or segment thereof to uses requiring less stringent water quality criteria. If seasonal uses are adopted, water quality criteria should be adjusted to reflect the seasonal uses, however, such criteria shall not preclude the attainment and maintenance of a more protective use in another season.

(g) States may remove a designated use which is *not* an existing use, as defined in § 131.3, or establish sub-categories of a use if the State can demonstrate that attaining the designated use is not feasible because:

(1) Naturally occurring pollutant concentrations prevent the attainment of the use; or

(2) Natural, ephemeral, intermittent or low flow conditions or water levels prevent the attainment of the use, unless these conditions may be compensated for by the discharge of sufficient volume of effluent discharges without violating State water conservation requirements to enable uses to be met; or

(3) Human caused conditions or sources of pollution prevent the attainment of the use and cannot be remedied or would cause more environmental damage to correct than to leave in place; or

(4) Dams, diversions or other types of hydrologic modifications preclude the attainment of the use, and it is not feasible to restore the water body to its original condition or to operate such modification in a way that would result in the attainment of the use; or

(5) Physical conditions related to the natural features of the water body, such as the lack of a proper substrate, cover, flow, depth, pools, riffles, and the like, unrelated to water quality, preclude attainment of aquatic life protection uses; or

(6) Controls more stringent than those required by sections 301(b) and 306 of the Act would result in substantial and widespread economic and social impact.

(h) States may not remove designated uses if:

(1) They are existing uses, as defined in § 131.3, unless a use requiring more stringent criteria is added; or

(2) Such uses will be attained by implementing effluent limits required under sections 301(b) and 306 of the Act and by implementing cost-effective and reasonable best management practices for nonpoint source control.

(i) Where existing water quality standards specify designated uses less than those which are presently being attained, the State shall revise its standards to reflect the uses actually being attained.

(j) A State must conduct a use attainability analysis as described in § 131.3(g) whenever:

(1) The State designates or has designated uses that do not include the uses specified in section 101(a)(2) of the Act, or

(2) The State wishes to remove a designated use that is specified in section 101(a)(2) of the Act or to adopt subcategories of uses specified in section 101(a)(2) of the Act which require less stringent criteria.

(k) A State is not required to conduct a use attainability analysis under this regulation whenever designating uses which include those specified in section 101(a)(2) of the Act.

§ 131.11 Criteria.

(a) *Inclusion of pollutants:* (1) States must adopt those water quality criteria that protect the designated use. Such criteria must be based on sound scientific rationale and must contain sufficient parameters or constituents to protect the designated use. For waters with multiple use designations, the criteria shall support the most sensitive use.

(2) *Toxic pollutants.* States must review water quality data and information on discharges to identify specific

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water bodies where toxic pollutants may be adversely affecting water quality or the attainment of the designated water use or where the levels of toxic pollutants are at a level to warrant concern and must adopt criteria for such toxic pollutants applicable to the water body sufficient to protect the designated use. Where a State adopts narrative criteria for toxic pollutants to protect designated uses, the State must provide information identifying the method by which the State intends to regulate point source discharges of toxic pollutants on water quality limited segments based on such narrative criteria. Such information may be included as part of the standards or may be included in documents generated by the State in response to the Water Quality Planning and Management Regulations (40 CFR part 35).

(b) Form of criteria: In establishing criteria, States should:

(1) Establish numerical values based on:

(i) 304(a) Guidance; or

(ii) 304(a) Guidance modified to reflect site-specific conditions; or

(iii) Other scientifically defensible methods;

(2) Establish narrative criteria or criteria based upon biomonitoring methods where numerical criteria cannot be established or to supplement numerical criteria.

§ 131.12 Antidegradation policy.

(a) The State shall develop and adopt a statewide antidegradation policy and identify the methods for implementing such policy pursuant to this subpart. The antidegradation policy and implementation methods shall, at a minimum, be consistent with the following:

(1) Existing instream water uses and the level of water quality necessary to protect the existing uses shall be maintained and protected.

(2) Where the quality of the waters exceed levels necessary to support propagation of fish, shellfish, and wildlife and recreation in and on the water, that quality shall be maintained and protected unless the State finds, after full satisfaction of the intergovernmental coordination and public participation provisions of the State's continuing planning process, that allowing lower water quality is necessary to accommodate important economic or social development in the area in which the waters are located. In allowing such degradation or lower water quality, the State shall assure water quality adequate to protect existing uses fully. Further, the State shall assure that there shall be achieved the highest statutory and regulatory requirements for all new and existing point sources and all cost-effective and reasonable best management practices for nonpoint source control.

(3) Where high quality waters constitute an outstanding National resource, such as waters of National and State parks and wildlife refuges and waters of exceptional recreational or ecological significance, that water quality shall be maintained and protected.

(4) In those cases where potential water quality impairment associated with a thermal discharge is involved, the antidegradation policy and implementing method shall be consistent with section 316 of the Act.

§ 131.13 General policies.

States may, at their discretion, include in their State standards, policies generally affecting their application and implementation, such as mixing zones, low flows and variances. Such policies are subject to EPA review and approval.

Subpart C—Procedures for Review and Revision of Water Quality Standards

§ 131.20 State review and revision of water quality standards.

(a) *State review.* The State shall from time to time, but at least once every three years, hold public hearings for the purpose of reviewing applicable water quality standards and, as appropriate, modifying and adopting standards. Any water body segment with water quality standards that do not include the uses specified in section 101(a)(2) of the Act shall be re-examined every three years to determine if any new information has become available. If such new information indicates that the uses specified in section