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**COURT OF APPEALS, DIVISION II
OF THE STATE OF WASHINGTON**

NORTHWEST PULP & PAPER ASSOCIATION,
THE ASSOCIATION OF WASHINGTON BUSINESS,
and WASHINGTON FARM BUREAU,

Petitioners,

v.

STATE OF WASHINGTON, DEPARTMENT OF ECOLOGY,

Respondent.

**PETITION FOR
DISCRETIONARY REVIEW**

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I. INTRODUCTION

The Washington Administrative Procedure Act (APA), chapter 34.05 RCW, requires notice and comment rulemaking to ensure that parties impacted by actions taken by regulatory agencies can meaningfully participate in the development of policies that affect them. The APA thus broadly defines a “rule” in RCW 34.05.010(16) to include *any* agency directive that is generally applicable to all members of a class or to all participants in an agency program, provided that the directive falls into one of five enumerated categories.

In 2018, the Department of Ecology issued a revised version of its Water Quality Program Permit Writer’s Manual with a new chapter 6, section 4.5 (the Test Methods Section), addressing, for the first time, the test methods to be used by Ecology permit writers to measure polychlorinated biphenyls (PCBs) in National Pollutant Discharge Elimination System (NPDES) permits. In a departure from past versions of the Manual, the Test Methods Section newly directed Ecology’s

permit writers to do exactly the opposite of what is required under federal and state regulations and use unreliable and inaccurate PCBs test methods 1668C and 8082A, which have not been approved by EPA. Rather than promulgate the Test Methods Section using APA-required rulemaking procedures, Ecology circumvented notice and comment by simply adding the new Test Methods Section to its Manual, thereby depriving the regulated community of the opportunity to weigh in on this impactful and complex requirement.

The Thurston County Superior Court dismissed Petitioners' APA rule challenge alleging that the Test Methods Section was an invalid rule adopted by Ecology without notice and comment rulemaking. The Court of Appeals affirmed. Even though the Manual, on its face, requires that permit writers follow its dictates when issuing and reissuing NPDES permits, and the Manual is applied to all participants in the state NPDES program discharging PCBs, the Court of Appeals held that the Test Methods Section is not a directive of general

applicability and thus does not meet the RCW 34.05.010(16) definition of a rule.

The published decision of the Court of Appeals, with its constricted reading of the “general applicability” requirement of RCW 34.05.010(16), is directly contrary to this Court’s decisions in *Failor’s Pharmacy v. Dep’t of Social and Health Servs.*, 125 Wn.2d 488, 495, 886 P.2d 147 (1994), and *Simpson Tacoma Kraft Co. v. Dep’t of Ecology*, 119 Wn.2d 640, 648, 835 P.2d 1030 (1992). The Court of Appeals effectively created a new test for “general applicability” that would shield many agency directives from the APA’s notice and comment rulemaking requirements, contrary to the very purpose behind those requirements. Here, because all NPDES permittees do not discharge PCBs, the Court of Appeals found that the Test Methods Section was not generally applicable and did not constitute a rule. But this cannot be the case. The “general applicability” rule applies to the class that is regulated, not the action being regulated. Every NPDES permit that regulates

PCBs is subject to the Test Methods Section. Given the importance of the APA's rulemaking requirements, which apply to every state agency, the Court of Appeals' decision in this case raises an issue of substantial public interest, warranting review and correction by this Court.

II. IDENTITY OF PETITIONER

Petitioners are appellants Northwest Pulp & Paper Association, the Association of Washington Business, and Washington Farm Bureau (collectively, Northwest Pulp & Paper).

III. CITATION TO COURT OF APPEALS DECISION

Northwest Pulp & Paper seeks review of the Court of Appeals, Division II published decision, dated December 14, 2021, attached as Appendix A.

IV. ISSUES PRESENTED FOR REVIEW

1. Whether the new Test Methods Section of Ecology's Permit Writer's Manual is a "directive of general applicability" within the meaning of the APA's definition

of a “rule” in RCW 34.05.010(16) where on its face the Manual applies to virtually all discharge permits issued by Ecology in Washington, and applies uniformly to all permittees discharging PCBs into Washington waterbodies.

2. Whether the new Test Methods Section of Ecology’s Permit Writer’s Manual falls into at least one of the five categories set out in the APA’s definition of a “rule” in RCW 34.05.010(16) where prior versions of the Manual contained no requirements regarding the use of PCBs test methods, and the Test Methods Section newly instructs permit writers, contrary to federal and state law, to use unapproved PCBs test methods 1668C and 8082A when issuing and reissuing NPDES permits.

V. STATEMENT OF THE CASE

A. The Clean Water Act and NPDES Permit Program.

The Clean Water Act, 33 U.S.C. §§ 1251-1388, prohibits the discharge of pollutants from a point source without an

NPDES permit. 33 U.S.C. §§ 1311(a), 1342(a). In Washington, Ecology has delegated responsibility for administering the NPDES permit program and drafting, issuing, and reissuing permits to all entities in the state discharging into waters of the United States outside of federal and tribal lands. RCW 90.48.260; 33 U.S.C. § 1342(b)(1)(B); 40 C.F.R. § 122.46(a); WAC 173-220-180(1). Dischargers must submit a permit application to Ecology. 40 C.F.R. § 122.21(a); WAC 173-220-040. Permittees whose permits are due to expire have a “duty to reapply” and obtain a new permit. 40 C.F.R. §§ 122.21(d), 122.41(b). *See* WAC 173-220-180(2).

An NPDES permit specifies water quality criteria and the required methods to apply it. WAC 173-201A-260(3).

Ecology has adopted water quality standards, chapter 173-201A WAC, that have been approved by EPA under the CWA. 33 U.S.C. § 1313. Among other requirements, NPDES permits must impose effluent limitations in order to ensure that the state’s water quality standards will not be violated. 33 U.S.C.

§§ 1311(b)(1)(C), 1342(a)-(b), 1362(11); 40 C.F.R. § 122.44;
WAC 173-226-070; WAC 173-201A-510(1)(b).

40 C.F.R. Part 122 regulates the manner in which Ecology determines whether an NPDES permit requires a water-quality based effluent limitation (“WQBEL”), including determining whether a discharge has a reasonable potential to cause or contribute to a violation of a narrative or numeric water quality standard. 40 C.F.R. §§ 122.44(d)(1)(i),(ii). If the analysis shows that there is a reasonable potential, the permit must include an effluent limit for that pollutant. 40 C.F.R. §§ 122.44(d)(1)(i),(iii),(iv); 122.44(k)(3).

It is a violation of the CWA to discharge a pollutant in excess of the effluent limitations in an NPDES permit or to violate any other condition in the permit. 33 U.S.C. § 1311(a); 40 C.F.R. § 122.41. Noncompliance by the permittee with any condition of the permit is grounds for enforcement action; for permit termination, revocation and reissuance, or modification; or denial of a permit renewal application. 33 U.S.C. §

1342(b)(1)(C); 40 C.F.R. §§ 122.41, 122.64. Similarly, it is a violation of a state waste discharge permit to violate any conditions of the permit. RCW 90.48.144; WAC 173-220-150(1)(c). *See also* RCW 90.48.080. Discharge monitoring and reporting are the primary means of ensuring compliance with permit limitations. *See* 33 U.S.C. § 1318(a); 40 C.F.R. §§ 122.41(j), (l)(4); WAC 173-220-210(1).

B. NPDES Permits Require Use of EPA-Approved Test Methods in 40 C.F.R. Part 136.

The test methods approved by EPA for measuring chemicals in effluent in NPDES permits are contained in 40 C.F.R. Part 136. It is undisputed that the only test method approved in 40 C.F.R. Part 136 for measuring PCBs is Method 608. 40 C.F.R. § 136.3 Table 1C, Part 136, Appendix A, Meth. 608. EPA has repeatedly declined to approve other test methods for measuring PCBs in NPDES permits, most recently in May 2021. 86 Fed. Reg. 27,226 (May 19, 2021); 82 Fed. Reg. 40,836, 40,875-76 (Aug. 28, 2017).

Under state and federal regulations Ecology “may also approve other [test] methods following consultation with adjacent states and with the approval of the USEPA.” WAC 173-201A-260(3)(h). *See* 40 C.F.R. §§ 136.4, 136.5, 136.6. Although Ecology has considered seeking EPA approval for an alternate PCBs test method, it has never done so. CP 27-30; CP 18-19. In the Test Methods Section Ecology stated that it is not proposing to seek EPA approval of Method 1668C “as there are known problems in regard to the repeatability and accuracy of the method in addition to the expense of the analysis.” AR 0164.0256.¹

Both state and federal regulations provide that NPDES permits “must” and “shall” use the EPA-approved test methods contained in 40 C.F.R. Part 136. Washington’s surface water quality standards identify the procedures Ecology must use

¹ “AR” references are to the Administrative Record certified by Ecology. The 2018 Manual is in the Administrative Record at AR 0164. The Test Methods Section is at AR 0164.0249-264.

when applying the appropriate state water quality criteria for a waterbody in an NPDES permit. WAC 173-201A-260(3). The standards state:

The analytical testing methods for these numeric criteria *must* be in accordance with the “*Guidelines Establishing Test Procedures for the Analysis of Pollutants*” (40 C.F.R. Part 136) or superseding methods published.

WAC 173-201A-260(3)(h) (emphasis supplied).

EPA’s regulations are consistent. 40 C.F.R. § 136.1 provides that 40 C.F.R. Part 136-approved test methods “shall . . . be used to perform the measurements” for permit applications, reports required to be submitted under permits, or requests for quantitative or qualitative effluent data. 40 C.F.R. § 136.1(a)(1), (2). Permit applications “shall not be considered complete unless all required quantitative data are collected in accordance with sufficiently sensitive analytical methods approved under 40 C.F.R. part 136. . . .” 40 C.F.R. § 122.21(e)(3). The EPA regulation setting out the “conditions applicable to all permits” also mandates that required permit monitoring “must be conducted according to test procedures

approved under 40 C.F.R. Part 136. . . .” 40 C.F.R. § 122.41(j)(4).

In August 2018, the Washington State Supreme Court held that because the CWA and state and federal regulations require that NPDES permits use EPA-approved test methods to measure PCBs, and Method 608 is the only such method, Ecology is required to use Method 608 in the permits it issues to dischargers. *Puget Soundkeeper Alliance v. Dep’t of Ecology*, 191 Wn.2d 631, 424 P.3d 1173 (2019) (“*Seattle Iron & Metals*”). The court stated: “Method 608 is EPA approved, and Ecology was required to use that test.” *Id.* at 642-43.

C. Ecology’s Test Methods Section.

Directly contrary to *Seattle Iron & Metals* and the regulations requiring the use of 40 C.F.R. part 136 EPA-approved test methods to measure PCBs, in July 2018 Ecology issued a revised version of the Manual, with the new Test Methods Section directing permit writers to use unapproved PCBs test methods for several purposes when writing NPDES

permits. AR 0164.0249-264. Most importantly, the Section directs permit writers to “use all valid and applicable data, including data collected using methods not approved under 40 C.F.R. Part 136 (e.g. Methods 1668C and 8082A)” in evaluating the reasonable potential to cause or contribute to a violation of water quality standards, and in calculating numeric effluent limits. AR 0164.0254-55, 261-63. Once calculated, those numeric effluent limits – based on data from unapproved test methods – become enforceable in any reissued permit after the current permit expires. Moreover, even when an NPDES permit does not contain a numeric effluent limitation for PCBs, once Ecology has determined – again based on data from unapproved test methods – that a discharge has a reasonable potential to cause or contribute to a violation of water quality standards, permittees may be determined to have violated permit conditions prohibiting such discharges.

As with past versions, the 2018 Manual begins by stating that “[P]ermit writers are required to use the procedures in this

manual for developing permits” and directs that permit writers who believe that a permitting situation requires a different process must discuss the alternative process with their supervisor. AR 0164.0004 (emphasis supplied). The Manual states that its “objectives and functions” include defining “the *requirements* for permits in Washington,” and providing “a central document to place new information, guidance, and *requirements* related to permitting.” AR 0164.0031 (emphasis supplied). In practice, “Ecology permit writers look to this Manual as the inviolate ‘rule book’ for NPDES permit development.” AR 0329.0001.

The Manual states that its requirements apply to all Joint State/NPDES permits issued by Ecology under the WPCA and CWA, all industrial/commercial facilities, all general permits, and all state waste discharge permits. AR 0164.0032. Ecology instructed its permit writers that they must use the new Test Methods Section “for all PCB monitoring in all water quality permits.” AR 0449.0003.

VI. ARGUMENT

This case merits discretionary review because the Court of Appeals' narrow reading of the APA's definition of a "rule" in RCW 34.05.010(16)(a) conflicts with Supreme Court decisions and involves an issue of substantial public interest that should be determined by the Court. *See* RAP 13.4(b)(1) and (4).

A. The Court of Appeals Decision Regarding the RCW 34.05.010(16) Definition of a Rule of General Applicability Conflicts with Supreme Court Decisions and Involves an Issue of Substantial Public Interest.

RCW 34.05.375 requires that an agency substantially comply with the APA rule-making procedures set out in RCW 34.05.310-.395, including notice and comment requirements. An agency's failure to do so is grounds for invalidation of the rule. RCW 34.05.570(2)(c); *Faylor's Pharmacy*, 125 Wn.2d at 493. It is undisputed that Ecology did not conduct notice and comment rulemaking here.

The purpose of APA-required rulemaking procedures is to give notice to the public of the proposed rule and to allow it

to comment on the proposal. *Hunter v. Univ. of Washington*, 101 Wn. App. 283, 293, 2 P.3d 1022 (2000). “Technically sound, lawful, and politically responsive rules are more likely if there is ample advance notice of the terms of proposed rules and a full opportunity for, and consideration of, public comment.” *Id.* (citing William R. Andersen, *The 1988 Washington Administrative Procedure Act – An Introduction*, 64 Wash. L. Rev. 781, 795 (1989)). The definition of “rule” under our state’s APA, “unlike that in the federal or other state APAs, is inclusive.” *Failor’s Pharmacy*, 125 Wn.2d at 493 (emphasis supplied). The label that an agency puts on its action is not determinative of whether it constitutes a rule. *McGee Guest Home, Inc. v. Dep’t of Social and Health Serv.*, 142 Wn.2d 316, 322, 12 P.3d 144 (2000).

Washington’s APA defines a “rule” as follows:

“Rule” means any agency order, directive, or regulation of general applicability (a) the violation of which subjects a person to a penalty or administrative sanction; (b) which establishes, alters, or revokes any procedure, practice, or requirement relating to agency hearings; (c)

which establishes, alters, or revokes any qualification or requirement relating to the enjoyment of benefits or privileges conferred by law; (d) which establishes, alters, or revokes any qualifications or standards for the issuance, suspension, or revocation of licenses to pursue any commercial activity, trade, or profession; or (e) which establishes, alters, or revokes any mandatory standards for any product or material which must be met before distribution or sale.

RCW 34.05.010(16).

RCW 34.05.010(16) begins with the requirement that a “rule” be an “order, directive, or regulation of general applicability.” The definition “goes beyond orders and regulations of general applicability and includes ‘directives,’ presumably referring to anything which is directive in nature, whether labeled a bulletin, an announcement, or a manual.” Andersen, 64 Wash. L. Rev. at 790.

The Washington Supreme Court set out the standard for “general applicability” in *Failor’s Pharmacy and Simpson Tacoma Kraft*: An agency action is of general applicability if applied uniformly to all members of a class, or applicable to all participants in a program. *Failor’s Pharmacy*, 125 Wn.2d at

495; *Simpson Tacoma Kraft*, 119 Wn.2d at 648. In these cases, the court drew a distinction between directives applied to just one individual or program participant, which are not considered rules, versus those applied to an entire class of individual or program participants, which are. Thus, “where the challenge is to a policy applicable to all participants in a program, not its implementation under a single contract or assessment of individual benefits, the action is of general applicability within the definition of a rule.” *Faylor’s Pharmacy*, 125 Wn.2d at 495 (citing *Simpson Tacoma Kraft*, 119 Wn.2d at 648).

The court first set out this “general applicability” standard in *Simpson Tacoma Kraft*, which involved Ecology’s adoption of a new numeric water quality standard for dioxin without engaging in APA rulemaking. 119 Wn.2d at 643-44. The court held that because Ecology applied its new water quality standard to all entities discharging dioxin into the state’s waters pursuant to NPDES permits, rather than to just one permittee, the standard was a rule of general applicability. *Id.*

at 647-48. Similarly, in *Failor's Pharmacy*, DSHS's changes to Medicaid reimbursement payment schedules for prescription drugs were held to be a rule of general applicability because the policy was applicable to all Medicaid prescription provider program participants and not just to a single participant.

Failor's Pharmacy, 125 Wn.2d at 495-96. Because the Test Methods Section requirements are applied to all dischargers discharging PCBs into the state's waters pursuant to the NPDES program, not just to one discharger, program participant, or permittee, it meets the standard for general applicability in *Failor's Pharmacy* and *Simpson Tacoma Kraft*.

The Court of Appeals decision here set out a new standard for "general applicability" not previously articulated by any Washington court:

Where the agency action provides guidance for agency staff that (1) allows staff to exercise discretion, (2) provides for case-by-case analysis of variables rather than uniform application of a standard, and (3) is not binding on the regulated community, the action does not constitute a directive of general applicability.

App. A at 13. Applying this new standard, the Court of Appeals found that the Test Methods Section was not a directive of “general applicability” and thus did not fall within the RCW 34.05.010(16) definition of a rule requiring notice and comment rulemaking. *Id.* at 17.²

The Court of Appeals relied in part on a prior Court of Appeals, Division II opinion, *Sudar v. Dep’t of Fish & Wildlife Comm’n*, 187 Wn. App. 22, 347 P.3d 1090 (2015). App. A at 12-13, 16-17. Like the Court of Appeals decision at issue here, *Sudar* created a standard for general applicability contrary to that set out in *Faylor’s Pharmacy* and *Simpson Tacoma Kraft*. The *Sudar* court held that to be of “general applicability” an agency action must have a “legally enforceable regulatory effect” and “[a]n agency policy is subject to challenge as a rule

²Of course, the Court of Appeals also failed to properly apply its own novel test. The Test Methods Section does not, in fact, allow staff to exercise discretion and does impose a binding regulation on all NPDES permit holders. *See supra* at 12-13.

pursuant to RCW 34.05.570(1) only when it imposes an independent regulatory mechanism that operates with the force of law.” *Sudar*, 187 Wn. App. at 31-34. The *Sudar* court found that the agency action at issue did not meet this standard and thus did not meet the RCW 34.05.010(16) definition of a rule. Quoting from *Sudar*, the Court of Appeals here held that “[i]mportantly, the [Test Methods Section] has ‘no legally enforceable regulatory effect’ on PCB dischargers, and dischargers cannot be penalized for violating the Manual.” App. A at 16-17 (quoting *Sudar*, 187 Wn. App. at 32).³

³ The facts of *Sudar* are also distinguishable. *Sudar* involved a Policy Statement, filed with the code reviser as required by RCW 34.05.230(4). 187 Wn. App. at 25-26. Policy Statements are advisory only and are exempt from judicial review. RCW 34.05.230(1). The Policy Statement was also issued by the Washington Fish and Wildlife Commission, which had no regulatory or enforcement authority. The Commission’s sole purpose was to develop policies to guide the Fish & Wildlife Department on salmon management, policies that would have no impact on fishers unless the Department promulgated implementing rules. 187 Wn. App. at 26-27, 31-33. Unlike the purely advisory Policy Statement in *Sudar*, the Test Methods Section is contained in a manual setting out the requirements for Ecology’s permit writers. And unlike the Commission,

The standard for “general applicability” set out by the Court of Appeals, Division II here and in *Sudar*, is contrary to the Supreme Court’s standard in *Failor’s Pharmacy* and *Simpson Tacoma Kraft*. First, nothing in these Supreme Court cases, nor in the language of RCW 34.05.010(16), limits the definition of a “rule” to agency actions that do not allow for any exercise of discretion in the rule’s application. To the contrary, rules often allow for some degree of agency discretion. For example, in *Hillis v. Dep’t of Ecology*, 131 Wn.2d 373, 932 P.2d 139 (1997) the Supreme Court held that new internal policies and procedures to be used by Ecology staff when assessing groundwater permit applications constituted rulemaking, even though Ecology’s decision whether to grant a

Ecology is the regulatory and enforcement agency with delegated authority to administer the entire NPDES program in Washington, including promulgation of rules and issuance, reissuance and enforcement of permits.

permit to withdraw groundwater was discretionary. 131 Wn.2d at 384, 398-99. Ecology in fact acknowledged in *Hillis* that its decisions on permit applications were of general applicability to all pending water right applicants. *Id.* at 398.

Nor is there any language in *Failor's Pharmacy, Simpson Tacoma Kraft*, or RCW 34.05.010(16) requiring that the agency action have “legally enforceable regulatory effect” or “impose an independent regulatory mechanism” in order to meet the definition of a rule. Such a standard would be directly contrary to the language of RCW 34.05.010(16), which states that the agency action may be an “order, directive, *or* regulation.” It is also contrary to the statute’s broad inclusion of five different enumerated categories of “rule,” only one of which involves agency actions “the violation of which subjects a person to a penalty or administrative sanction.” RCW 34.05.010(16)(a). Finally, it is contrary to cases holding that a regulation can meet the state APA’s definition of a rule even where there are no penalties or sanctions imposed for its violation. *Assoc. of*

Wash. Bus. v. Dep't of Revenue, 121 Wn. App. 766, 773, 90 P.3d 1128 (2004), *aff'd as modified*, 155 Wn.2d 430, 120 P.3d 46 (2005). Under the Court of Appeals' constricted reading of RCW 34.05.010(16) it is difficult to conceive of *any* agency action, other than that made in the form of an order or regulation, that would constitute a "rule." Here, the Court of Appeals' opinion sanctions an agency's incorporation of a requirement into so-called "guidance" because the requirement applies to only a subset of a group (i.e., dischargers of PCBs) and because there is some allowance of discretion (i.e., permit writers must check with their managers). In the Manual, the limited exceptions available prove the rule.

The case also warrants review under RAP 13.4(b)(4) because ensuring that the courts utilize the proper standard for determining whether an agency action falls within the APA's definition of a rule is a matter of substantial public interest. Under the APA, rule challenges must be brought in Thurston County Superior Court. RCW 34.05.570(2)(b)(i). Any appeals

from that superior court are to the Division II Court of Appeals. The decisions of Division II thus dictate which agency actions must be subject to notice and comment rulemaking. Division II, first in *Sudar* and now in the decision at issue here, has created and is applying a new and narrow interpretation of RCW 34.05.010(16) likely to shield a wide range of agency actions from rulemaking, depriving the public of the participation and process intended by the legislature when enacting the APA.⁴ Acceptance of review by the supreme court to ensure that Division II applies the correct standard for determining whether an agency action is a rule will ensure that all state agencies engage in the required public process in promulgating rules.

⁴ The importance attached by the legislature to public involvement in agency rule-making process is further illustrated by its 1995 regulatory reform legislation, which created a category of “significant legislative rules” requiring a higher level of procedural requirements. RCW 34.05.328(1). The statute applies to Ecology’s actions. RCW 34.05.328(5)(a)(i).

B. Whether the Test Methods Section Falls Within One of the Enumerated Categories of RCW 34.05.010(16) Is An Issue of Substantial Public Interest.

The Court of Appeals rested its entire decision on its determination that the Test Methods Section was not “generally applicable,” declining to consider whether the Test Methods Section falls within one of the five enumerated categories in RCW 34.05.010(16). App. A at 17. As with the issue of “general applicability”, resolution of this issue impacts whether state agencies may shield their actions from notice and comment rulemaking and is of substantial public interest appropriate for review. *See* RAP 13.4(b)(4).

The Test Method Section’s directives are directly contrary to federal and state regulations and *Seattle Iron & Metals*. The Test Methods Section “establishes, alters, or revokes any qualifications or standards for the issuance, suspension or revocation of licenses to pursue any commercial

activity. . . .”, and thus falls within RCW 34.05.010(16)(d).⁵ Entities discharging or proposing to discharge pollutants are under a “duty to apply” for an NPDES permit, must submit a “complete application” in order to fulfill this duty, and have a duty to reapply when their permits expire. 40 C.F.R. §§ 122.21(a)(1), 122.21(d), 122.41(b). The CWA and federal regulations set out the qualifications and standards for permit issuance and reissuance, and unequivocally require the use of EPA-approved test methods. In *Seattle Iron & Metals*, the Supreme Court confirmed that WAC 173-201A-260(3) similarly requires the use of EPA-approved test methods. The Test Methods Section alters those qualifications and standards.⁶

⁵ The APA definition of “license” includes a “permit.” RCW 34.05.010(9)(a).

⁶ Although it need only fall within one of the categories set out in RCW 34.05.010(16), the Test Methods Section also falls within RCW 34.05.010(16)(c). *See Hillis*, 131 Wn.2d at 398-99.

The Supreme Court recognized the broad public import of the issue of what PCBs test methods must be used in NPDES permits when it accepted discretionary review in *Seattle Iron & Metals*. Five *amici curiae* briefs were filed in that appeal, illustrating the importance of the issue to a broad spectrum of the public, including governmental and private NPDES permittees, environmental groups, and tribes. *Seattle Iron & Metals*, 191 Wn.2d at 632-33. The case at hand presents an even stronger argument for substantial public interest, because while *Seattle Iron & Metals* involved one individual permit, at issue here are the dictates of the Manual, which apply to virtually all discharge permits. The importance of the PCBs test methods issue is further illustrated by the sheer number of NPDES permittees represented by each petitioner association. *See* CP 24-25.

Resolution of the issue here is urgent. Ecology's permit writers currently follow the dictates of the Test Methods Section and require unapproved methods 1668C and 8082A in

issuing and reissuing permits. For example, the 2016 draft permits for the five permittees discharging PCBs into the Spokane River contained, for the first time, numeric effluent limitations for PCBs based on unapproved test method data collected pursuant to the expiring permits. S2663-64, S2680-81; AR 0040.000-03, 1499.0007.⁷ The draft permits also continue to require monitoring of PCBs using 1668C. S2666-68, S2672, S2678; AR 0040.000-03. While those permits have not been issued, the Test Methods Section requires Ecology to use data from unapproved test methods to characterize effluent, assess technology requirements, perform reasonable potential analysis, and derive numeric effluent. Likewise, permittees throughout the state are at risk of being found in violation of the CWA and subject to enforcement actions by Ecology and third

⁷ “S” references are to Supplemental Record documents. *See* CP 2027-29, 2030-38.

parties based on unreliable data obtained from monitoring using unapproved test methods required by the Test Methods Section.

VII. CONCLUSION

For the foregoing reasons, Northwest Pulp & Paper respectfully requests that the Supreme Court grant this petition for discretionary review.

This document complies with the word limit of RAP 18.17(c)(10) because, excluding the parts of the document exempted by RAP 18.17(b) and RAP 18.17(c), this document contains 4,587 words.

Respectfully submitted this 13th day of January 2022.

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DECLARATION OF SERVICE

I declare under penalty of perjury under the laws of the State of Washington that on this date I caused the foregoing document to be served on the following parties via the method and date indicated:

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Dated at Seattle, Washington, this 13th day of January 2022.

s/Pamela Ruggles
Pamela Ruggles, Paralegal

Appendix A

December 14, 2021

IN THE COURT OF APPEALS OF THE STATE OF WASHINGTON

DIVISION II

NORTHWEST PULP & PAPER
ASSOCIATION; THE ASSOCIATION OF
WASHINGTON BUSINESS; AND
WASHINGTON FARM BUREAU,

Appellants,

v.

STATE OF WASHINGTON, DEPARTMENT
OF ECOLOGY,

Respondent.

No. 55164-1-II

PUBLISHED OPINION

GLASGOW, A.C.J.—In July 2018, the Department of Ecology added a new section, chapter 6, section 4.5 (Section 4.5), to its Water Quality Program Permit Writer’s Manual to specifically address the release of polychlorinated biphenyls (PCBs) into Washington’s surface waters. To identify and measure the presence of PCBs in surface waters, Section 4.5 allows the use of testing Methods 1668C and 8082A, which are particularly sensitive, in addition to Method 608.3, the method expressly authorized in federal regulation.

Northwest Pulp & Paper Association, Association of Washington Business, and Washington Farm Bureau (hereinafter collectively referred to as Northwest Pulp & Paper) petitioned for judicial review and declaratory judgment under the Washington Administrative Procedure Act (APA), chapter 34.05 RCW, asking the superior court to invalidate Section 4.5. Northwest Pulp & Paper argued Section 4.5 is an invalid rule under the APA because Ecology

failed to comply with the procedural requirements for rule making, Ecology exceeded its authority, and the section is arbitrary and capricious. The superior court dismissed the petition and denied the request for declaratory judgment, concluding that Section 4.5 is not a rule under the APA.

We hold Section 4.5 is guidance for agency staff, not a rule subject to the APA's rule-making requirements. We affirm.

BACKGROUND

I. PCBs, POLLUTANT DISCHARGE PERMITS, AND STATE WATER QUALITY

“Banned since the 1970s, PCBs are manufactured toxic chemicals that persist in the environment and are capable of bioaccumulation and biomagnification: they increase in concentration in individual organisms and with each successive level of the food chain.” *Puget Soundkeeper All. v. Dep’t of Ecology*, 191 Wn.2d 631, 635, 424 P.3d 1173 (2018) (*Seattle Iron & Metals*). Some PCBs are likely carcinogens that are harmful to humans.

The federal Clean Water Act (also known as the Federal Water Pollution Control Act), 33 U.S.C. §§ 1251-1388, seeks “to restore and maintain the chemical, physical, and biological integrity of the Nation’s waters” by regulating the discharge of pollutants, including PCBs. 33 U.S.C. § 1251(a); 40 C.F.R. § 129.4(f). Under the Clean Water Act, it is unlawful to discharge any pollutant into the water unless the discharger has applied for and received a National Pollutant Discharge Elimination System (NPDES) permit. 33 U.S.C. §§ 1311(a), 1342(a)(1). In Washington, responsibility for controlling state water pollution and administering the NPDES permit program is delegated to Ecology. 33 U.S.C. § 1342(b); RCW 90.48.260(1).

Ecology has established state water quality standards to protect surface waters in Washington. *See* chapter 173-201A WAC. Water quality standards set contaminant concentration

limits in surface water, ground water, and sediment, for example. These standards include both narrative and numeric criteria. WAC 173-201A-010(1)(a). Washington's narrative standard for toxic substances provides, "Toxic substances shall not be introduced above natural background levels in waters of the state which have the potential either singularly or cumulatively to adversely affect characteristic water uses, cause acute or chronic toxicity to the most sensitive biota dependent upon those waters, or adversely affect public health." WAC 173-201A-240(1).

Initially, Washington's numeric standards for toxic substances included acute and chronic criteria for freshwater and marine water to protect aquatic life. Ecology has since promulgated a rule that added numeric criteria to protect human health. One numeric criterion for protecting human health currently provides that the total PCBs in a body of surface water should be limited to 0.00017 µg/L (micrograms per liter). WAC 173-201A-240(5) tbl.240.

II. MANAGING PCB POLLUTION

A. Effluent Limits and Best Management Practices

If a discharger violates or has the "reasonable potential" to violate water quality standards by discharging a particular pollutant, then the discharger's NPDES permit must contain effluent limitations for that pollutant. 40 C.F.R. § 122.44(d)(1)(iii). An "effluent limitation" is "any restriction . . . on quantities, rates, and concentrations of chemical, physical, biological, and other constituents which are discharged from point sources into surface waters of the state." WAC 173-220-030(9). Effluent limitations may be technology based, meaning they are "based on the capability of a treatment method to reduce the pollutant to a certain concentration." Administrative Record (AR) at 0164.0029. They may also be water quality based, meaning they are based on

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limiting the concentration of effluent “such that it will not cause a violation of water quality standards.” AR at 0164.0030.

The legislature has required, “In no event shall the discharge of toxicants be allowed that would violate any water quality standard.” RCW 90.48.520. NPDES permits “must be conditioned so the discharges authorized will meet the water quality standards. No waste discharge permit can be issued that causes or contributes to a violation of water quality criteria.” WAC 173-201A-510(1). The policy goal of prohibiting any and all violations of state water quality standards remains difficult to attain in practice, however. “Ecology sets maximum effluent limits for certain pollutants at numbers presently undetectable and unquantifiable in order to encourage scientific progress toward the goal of cleaner and safer water.” *Seattle Iron & Metals*, 191 Wn.2d at 643.

In addition to effluent limitations, a permit may require the discharger to use best management practices to prevent the discharge of pollutants. Best management practices may include specific treatment requirements, maintenance and operating procedures, or strategies to control runoff, leaks, and spillage. 40 C.F.R. § 122.2. Permits may require dischargers to comply with narrative conditions that “complement numeric limits,” such as requirements to “study the efficiency of the treatment system” or to “develop a plan to identify and implement pollution prevention that is technically and economically achievable.” *Puget Soundkeepers All. v. Dep’t of Ecology*, 102 Wn. App. 783, 794-95, 9 P.3d 892 (2000).

Ecology’s Water Quality Program recommended a new permitting approach for PCBs in 2016 that “requires dischargers to use improved detection methods to find PCBs in waste streams” and to use updated best management practices, based on guidance from the Environmental Protection Agency (EPA) and “on-the-ground experience,” to prevent PCB pollution. AR at

0843.0001. The recommended changes were to the methods for detecting PCBs, not PCB effluent limits. However, the program recognized that these changes will “have eventual ramifications to all water quality permittees with PCB limits” because more sensitive methods of monitoring will “turn up previously unseen PCBs in discharges,” which “could drive new permit limits and violations.” AR at 0843.0001, .0003.

B. Test Methods for Detecting PCBs

Congress tasked the EPA with “promulgat[ing] guidelines establishing test procedures for the analysis of pollutants.” 33 U.S.C. § 1314(h); 40 C.F.R. § 122.2. Those test methods are established in 40 C.F.R. part 136. Currently, the only test method for measuring PCBs that is approved under part 136 is Method 608.3. 40 C.F.R. § 136.3, tbl.IC.¹ The description of Method 608.3 in appendix A of part 136 explains that the “EPA has promulgated this method . . . for use in wastewater compliance monitoring under the [NPDES]” permitting system. 40 C.F.R. Pt. 136, App. A, Method 608.3, at 1.6.1.

Yet, as Ecology explains in its Permit Writer’s Manual, surface water quality standards to protect aquatic life and human health are set at levels lower than Method 608.3 is able to detect and quantify. Method 608.3 is able to reliably detect a concentration of 0.065 micrograms of PCBs per liter of water. This means water could contain approximately 382 times more PCBs than the state numeric criterion necessary to protect human health of 0.00017 µg/L, yet the PCBs would

¹ Table IC references both Method 608.3 and Method 625.1. Method 608.3 is specifically “for determination of organochlorine pesticides and [PCBs] in industrial discharges and other environmental samples,” whereas Method 625.1 is more generally “for determination of semivolatile organic pollutants in industrial discharges and other environmental samples.” 40 C.F.R. Pt. 136, App. A, Method 608.3, at 1.1, Method 625.1, at 1.1. The description of Method 625.1 clarifies that “Method 608.3 should be used for determination of pesticides and PCBs.” 40 C.F.R. Pt. 136, App. A, Method 625.1, at 1.4.

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not be detectable using Method 608.3. *Cf. Seattle Iron & Metals*, 191 Wn.2d at 638 (addressing an argument that monitoring using Method 608 (a precursor to Method 608.3) was insufficient because “the test cannot ensure a permit holder complies with statutory water quality standards”).

Two testing methods exist for measuring PCBs that are more sensitive. Methods 8082A and 1668C “provide lower analytical limits” than Method 608.3. AR at 0164.0250. Although Method 608.3 is the only method that can be used under 40 C.F.R. part 136 to determine compliance with numeric effluent limits, Methods 8082A and 1668C may be used for purposes other than determining compliance.

For example, Method 1668C can be used for “monitoring of final effluents for PCB congeners.” AR at 0277.0028; *see also* 40 C.F.R. Pt. 136, App. A, Method 608.3, at 1.5 (“Method 1668C . . . may be useful for determination of PCBs as individual chlorinated biphenyl congeners,” although Method 1668C has “not been approved for use at 40 [C.F.R.] part 136.”). PCBs consist of “209 individual compounds known as congeners.” AR at 0922.0004. Mixtures of these compounds were commercially produced, and the mixtures are known by their trade names, most commonly Aroclor. Water quality based effluent limits consider the concentration of total PCBs in the water, and Method 608.3, the part 136-approved method for analyzing PCBs, measures the total concentration of Aroclors in the water. In contrast, Method 1668C is a “very sensitive analytical method that has the capability of detecting 209 different PCB congeners.” AR at 0164.0254. The EPA has explained that because there is no part 136-approved method for measuring individual congeners, Ecology has “flexibility to require the use of EPA Method 1668C for monitoring of PCB congeners.” AR at 0277.0028.

III. SECTION 4.5 OF THE PERMIT WRITER'S MANUAL

In 2018, Ecology issued a revised version of its Permit Writer's Manual. A cover letter from the Water Quality Program Manager states that this Manual "describes Ecology's procedures when issuing permits for wastewater discharges. Permit writers are required to use the procedures in this manual for developing permits." AR at 0164.0004. However, "[i]f a permit writer believes a permitting situation requires a different process than in the manual, the permit writer should discuss the alternative process with their supervisor." AR at 0164.0004.

The Manual's "Note to Readers" describes it as "a working document for people at [Ecology] who write wastewater discharge permits," and the Manual's introduction similarly classifies it as "a technical guidance and policy manual for permit writers" that aims "to enhance the quality and consistency of the wastewater discharge permits issued by Ecology and to improve the efficiency of the permitting process." AR at 0164.0017, .0031 (boldface omitted). The introduction clarifies that the Manual "is not regulation and should not be cited as regulatory authority for any permit condition." AR at 0164.0033. Rather, the Manual "describes law and regulation pertaining to permitting," which "must be followed to issue a legal permit." *Id.* "Where those laws and regulations are not explicit on implementation the manual describes a process for implementation" that has been developed by Ecology, but "[i]f the process does not fit a permitting circumstance, the permit writer can explore alternative processes as long as the law and regulation are met." *Id.* Permit writers are expected to "exercise a considerable amount of discretionary authority" and "good judgment." AR at 0164.0036-.0037.

The Manual describes the test methods for identifying and measuring PCBs as "evolving rapidly." AR at 0164.0242. Ecology added Section 4.5 to the Manual in 2018 to specifically

address methods for identifying and measuring PCBs. The Manual emphasizes that only test methods approved under 40 C.F.R. part 136 can be used for permit applications and permit compliance monitoring, consistent with federal regulation. Because Method 608 (now 608.3) is the only method for analyzing PCBs that is approved under part 136, Section 4.5 repeatedly states that it must be used for permit applications and for monitoring compliance with numeric effluent limits for PCBs. *See, e.g.*, AR at 0164.0249, .0256, .0261-.0263.²

The Manual clearly states that Methods 8082A and 1668C cannot be used to evaluate compliance with numeric effluent limits for PCBs. However, the Manual presents Methods 8082A and 1668C, along with Method 608.3, as “the three methods that are used for permitting purposes.” AR at 0164.0249. Because water quality standards for PCBs are lower than Method 608.3 can evaluate, and Methods 8082A and 1668C “provide lower analytical limits,” Ecology advises that Methods 8082A and 1668C may be used for purposes other than evaluating compliance. AR at 0164.0250.

For example, Section 4.5 specifically advises permit writers to “[u]se all valid and applicable data, including data collected using methods not approved under 40 [C.F.R.] Part 136 (e.g. Methods 1668C and 8082A),” to evaluate whether a discharger’s effluent has the reasonable potential to violate a water quality standard and to calculate appropriate numeric effluent limits for permits. AR at 0164.0261-.0262. Section 4.5 also allows permit writers to evaluate the effectiveness of best management practices using “methods appropriate” for this purpose. AR at 0164.0263. This method selection “will depend on expected concentrations in the sampled media,

² At the time of the Manual’s publication, Method 608, an earlier iteration of Method 608.3, was still permitted as laboratories were in the process of receiving accreditation for Method 608.3.

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the [practices] required or selected, and the potential sources of PCBs on and to the site or facility.” AR at 0164.0264. And it may be appropriate to use Method 1668C where “identification of sources based on congener profile is necessary.” AR at 0164.0263.

With Method 1668C specifically, Ecology explains that it is “*not* proposing to seek EPA approval of this method under 40 [C.F.R.] part 136.5,” which provides for approval of alternate methods for limited regional use, “as there are known problems in regards to the repeatability and accuracy of the method in addition to the expense of the analysis.” AR at 0164.0256. But Ecology recognizes that “targeted monitoring under Method 1668C” may be “useful for identifying PCB sources” or “evaluating the effectiveness of a best management practice,” two activities that are separate from compliance monitoring. AR at 0164.0257.

A quality assurance project plan is required when using Method 1668C for any purpose, and it is recommended when using Method 8082A. These plans “ensure that the collected environmental data can be used for making decisions.” *Id.* They detail the processes necessary for “data collection, management[,] and subsequent analysis,” and they develop standard operating procedures “to evaluate and control data accuracy.” AR at 0164.0258. Procedures such as measuring the PCBs present in distilled water (blanks) for comparison “increase result precision” and “ensure no contamination occurs at any point during the analytical procedure.” AR at 0164.0255.

Subsection 4.5.4 provides additional guidance that permit writers “should consider . . . when requiring monitoring using either [M]ethod 8082A or 1668C.” AR at 0164.0257. For example, before requiring additional data collection, the permit writer should consider “the question the additional monitoring is going to attempt to answer and what kind of data is needed

to meet that end.” *Id.* Some monitoring may be done to assist with making a decision, while other monitoring may serve to estimate the scope of a problem. Additionally, while Method 1668C is the most sensitive method, it is also the most expensive. Therefore, “it is not necessarily appropriate to require this method when [M]ethod 8082A will also return detectible concentrations.” AR at 0164.0260. “Information collected through previous monitoring should help the permit writer understand which method to select.” *Id.*

Section 4.5.5 further advises permit writers on how to select the appropriate analytical test method and instructs permit writers to “[o]nly include monitoring requirements when necessary for the facility and its specific discharge situation.” *Id.* If dischargers are unlikely to have PCBs in their effluent at levels that would violate water quality standards, then “PCB monitoring may not be necessary.” *Id.* “While PCB monitoring may be appropriate for some dischargers based on individual facility characteristics, permit writers should consider the value and purpose of requiring PCB monitoring when developing discharge permits.” AR at 0164.0261.

Thus, Section 4.5 requires that only Method 608.3 be used to ultimately determine compliance with PCB effluent limits, but the more sensitive test Methods, 8082A and 1668C, can be used for other purposes in the course of the permitting process.

ANALYSIS

PROMULGATING A “RULE” UNDER THE APA

Northwest Pulp & Paper argues that when Ecology added Section 4.5 to the 2018 version of its Permit Writer’s Manual, it promulgated a rule that is invalid under RCW 34.05.570(2)(c). Northwest Pulp & Paper argues Section 4.5 is an invalid rule because it was adopted without compliance with statutory rule-making procedures and because Ecology’s decision to allow permit

writers to require the use of test methods that are not approved under 40 C.F.R. part 136 exceeds the agency's authority and is arbitrary and capricious. We disagree. Section 4.5 is not a rule, and RCW 34.05.570(2)(c) does not apply.³

A. Defining a "Rule" Under the APA

To be valid, a rule must comply with the requirements of the APA. RCW 34.05.375. We may invalidate a rule if it was adopted without compliance with statutory rule-making procedures, if its promulgation exceeded the agency's authority, or if it is arbitrary and capricious. RCW 34.05.570(2)(c). We review the validity of a rule de novo. *Ctr. for Biological Diversity v. Dep't of Fish & Wildlife*, 14 Wn. App. 2d 945, 967, 474 P.3d 1107 (2020).

As a preliminary matter, however, we must determine whether the challenged agency action in this case falls within the APA's definition of a "rule." To determine whether an agency action constitutes a rule under the APA, we look to the Act's statutory definition. *McGee Guest Home, Inc. v. Dep't of Soc. & Health Servs.*, 142 Wn.2d 316, 322, 12 P.3d 144 (2000). The label the agency assigns to the action is not determinative. *Id.*

Under the APA, there are two elements of a rule. For an agency action to qualify as a rule, it must be an "agency order, directive, or regulation of general applicability," and it must fall into one of five enumerated categories. RCW 34.05.010(16); *see also Failor's Pharmacy v. Dep't of Soc. & Health Servs.*, 125 Wn.2d 488, 494, 886 P.2d 147 (1994). An agency action is not a rule if

³ Northwest Pulp & Paper conceded that if Section 4.5 is not a rule, this rule challenge fails. During oral argument, Northwest Pulp & Paper explained that RCW 34.05.570(4), addressing other agency action, is not a basis it is relying on for this challenge. *See* Wash. Court of Appeals oral argument, *Northwest Pulp & Paper v. Dep't of Ecology*, No. 55164-1-II (Sept. 10, 2021), at 10 min., 55 sec. through 12 min., 42 sec., *audio recording*, TVW, Washington State's Public Affairs Network, <https://www.tvw.org/watch/?eventID=2021091014>.

it consists of “statements concerning only the internal management of an agency and not affecting private rights or procedures available to the public.” RCW 34.05.010(16)(i).

1. Directive of general applicability

An agency action is a directive of general applicability if it is “applied uniformly to all members of a class.” *Failor’s Pharmacy*, 125 Wn.2d at 495. For example, in *Simpson Tacoma Kraft Co. v. Department of Ecology*, Ecology instituted a numeric limit on the discharge of dioxin and “uniformly applie[d]” that limit to “all entities which discharge dioxin into the state’s waters, regardless of which entity or water body is at issue.” 119 Wn.2d 640, 648, 835 P.2d 1030 (1992). The Supreme Court concluded that this was a directive of general applicability because Ecology applied the standard “uniformly to the entire class of entities which discharges dioxin into the state’s water.” *Id.*

How the agency applies the challenged standard, not the outcome of the application, is determinative. The outcomes for individual entities may differ even when a standard is uniformly applied. For example, in *Failor’s Pharmacy*, Medicaid prescription service providers challenged amendments to reimbursement payment schedules. 125 Wn.2d at 490. Although the amount that each service provider was reimbursed differed based on factors such as the number of prescriptions they dispensed per year, each amount was determined by the agency applying the same, uniformly applicable, reimbursement schedules. *See id.* at 491-92. Thus, the schedules were directives of general applicability. *Id.* at 495-96.

In contrast, this court has held that an agency action is not a directive of general applicability where the challenged action is a document “written to guide agency staff” that “does not require strict adherence.” *Sudar v. Dep’t of Fish & Wildlife Comm’n*, 187 Wn. App. 22, 31-32,

347 P.3d 1090 (2015). In *Sudar*, petitioners challenged a policy document that the Department of Fish and Wildlife Commission developed to “guide the Department [of Fish and Wildlife] in its management of state resources,” including its “adoption of fishery rules.” *Id.* at 25-26. But the policy document itself had “no legally enforceable regulatory effect on fishers.” *Id.* at 32. Its objectives were “unenforceable until and unless the Department promulgate[d] rules” implementing them, and a fisher could not be penalized for violating the policy document. *Id.* Department staff were not bound by the policy document either. *Id.* at 33.

In sum, not every agency action carries the force of a rule. Where the agency action provides guidance for agency staff that (1) allows staff to exercise discretion, (2) provides for case-by-case analysis of variables rather than uniform application of a standard, and (3) is not binding on the regulated community, the action does not constitute a directive of general applicability.

- a. Section 4.5 does not mandate use of Methods 8082A and 1668C, and instead it contemplates permit writer discretion

When Section 4.5 addresses which testing methods should be used for various purposes, it only employs mandatory language to specify when regulations require use of Method 608.3. The section is clear that Method 608.3 must be used in permit applications and to monitor compliance with numeric effluent limits because these requirements are established in federal regulations.

For all other purposes, Section 4.5 allows for flexibility and discretion in determining which testing methods will be required in an individual permit or permitting process. For example, Methods 8082A and 1668C “*may* be used for permitting purposes to evaluate sources [of PCB pollution], but not for numeric effluent limit compliance.” AR at 0164.0250 (emphasis added). “For the purposes of applying [all known and reasonable technologies to control pollution], Method 1668C *may be required*,” but this depends on the need to identify individual congeners,

whether the expected concentrations of PCBs can be detected or quantified by Method 608.3, and the specific water treatment goals. AR at 0164.0263 (emphasis added). Permits also “*may require* monitoring using two different methods for two different purposes (e.g., Method 608.3 for monitoring to assess compliance with a numeric effluent limit and Methods 1668C or 8082A for [best management practices] effectiveness monitoring).” AR at 0164.0264 (emphasis added). The Manual advises the permit writer to “consider the result [they] want to achieve and the appropriateness of additional sampling.” AR at 0164.0260. Permit writers are expected to “exercise a considerable amount of discretionary authority” and “good judgment.” AR at 0164.0036-.0037. The plain language of Section 4.5 does not mandate use of Methods 8082A or 1668C. Instead, the decision to require use of these methods is within the permit writer’s discretion.

b. Section 4.5 does not contain a uniformly applicable standard

Unlike in *Simpson and Failor’s Pharmacy*, Section 4.5 does not require permit writers to uniformly impose PCB testing requirements on all entities discharging any amount of PCBs into any body of water. The Manual expressly states that “PCB monitoring may not be necessary” if the PCBs in a discharger’s effluent are unlikely to violate water quality standards, and it instructs permit writers to “[o]nly include monitoring requirements when necessary for the facility and its specific discharge situation.” AR at 0164.0260.

The decision of whether to require any additional testing for PCBs will depend on multiple site-specific variables. Permit writers should consider the discharging facility’s size, the possibility of preexisting pollution in the water, the type of pollutants involved, and what benefit additional monitoring would offer “before requiring PCB characterization in permits.” *Id.*

If permit writers do decide to impose additional testing to monitor the presence of PCBs, Section 4.5 instructs them to again consider site-specific variables and to exercise discretion. For example, when evaluating the effectiveness of best management practices, a permit writer's method selection will depend on the expected concentrations of pollutants in the water, the best practices required of the discharger, and the potential sources of PCBs. Section 4.5 advises that “[i]nformation collected through previous monitoring should help the permit writer understand which method to select.” *Id.*

The Manual also recognizes that the costs of different testing methods vary substantially, with Method 1668C being the most expensive. Therefore, it cautions that while Method 1668C “will return information down to the lowest quantifiable level, it is not necessarily appropriate to require this method when [M]ethod 8082A will also return detectible concentrations.” *Id.*

In *Failor's Pharmacy*, outcomes differed for the individual entities being regulated, but the same reimbursement schedules were imposed on all members of the regulated community. Here, individual outcomes differ because permit writers are considering and imposing different obligations within each permit—under the Manual's guidance—after reviewing site-specific conditions. Even though permit writers are instructed to use the guidance in the Manual ““for all PCB monitoring in all water quality permits,”” there is no uniform directive within the Manual that requires permit writers to impose testing Method 1668C or 8082A. Appellants' Opening Br. at 33 (emphasis omitted) (quoting AR at 0449.0003).

The Manual instructs permit writers to “[u]se all valid and applicable data, including data collected using methods not approved under 40 [C.F.R.] Part 136 (e.g. Methods 1668C and 8082A)” to evaluate whether a discharger's effluent has the reasonable potential to violate a water

quality standard and to calculate appropriate numeric effluent limits for permits. AR at 0164.0261-.0262. Northwest Pulp & Paper argues this language “directs and requires permit writers to use unapproved test methods” for these purposes. Appellants’ Opening Br. at 25. This language requires only that permit writers use all available data to make the most informed decisions possible. The Manual does not state that permit writers must mandate data collection using Methods 1668C and 8082A where such data does not already exist.

Moreover, a state policy goal is to prevent all discharges that cause or contribute to a violation of water quality standards. RCW 90.48.520; WAC 173-201A-510(1). Requiring permit writers to use all valid and applicable data to evaluate the reasonable potential of a discharge to violate water quality standards is one way to achieve this stated goal. As explained above, Method 608.3 can detect PCBs at a concentration of 0.065 µg/L, but the state numeric criterion for human health is 0.00017 µg/L. If Ecology cannot use data collected using more sensitive test methods, then Ecology cannot know when a permittee is discharging PCBs at a concentration lower than 0.065 µg/L yet higher than the water quality criterion of 0.00017 µg/L. The development of numeric effluent limits for each permit is Ecology’s responsibility under the law, and the Supreme Court has affirmed that “Ecology may use any data gathered in the past for its decision making on permits.” *Hillis v. Dep’t of Ecology*, 131 Wn.2d 373, 400, 932 P.2d 139 (1997).

Section 4.5 does not uniformly require PCB testing, nor does it require uniform application of a specific standard to determine what testing method should be used in a particular circumstance.

c. Section 4.5 has no regulatory effect, instead it is guidance for permit writers

The Manual is intended to *guide* use of the more sensitive testing methods in permitting. Importantly, Section 4.5 has “no legally enforceable regulatory effect” on PCB dischargers, and

dischargers cannot be penalized for violating the Manual. *Sudar*, 187 Wn. App. at 32. Only a violation of a specific NPDES permit condition will subject a discharger to an enforcement action.

Like the policy at issue in *Sudar*, Section 4.5 is “written to guide agency staff,” and it “does not require strict adherence” with its guidance. *Id.* at 31-32. Although the Manual’s preliminary note requires permit writers to use its listed procedures, the note also contemplates that permit writers may deviate from those procedures. “If a permit writer believes a permitting situation requires a different process than in the manual,” then they are instructed to “discuss the alternative process with their supervisor.” AR at 0164.0004. This is reiterated in the Manual’s introductory section, which explains that the Manual “is not regulation” but it “describes law and regulation pertaining to permitting.” AR at 0164.0033. “If the process does not fit a permitting circumstance, the permit writer can explore alternative processes as long as the law and regulation are met.” *Id.*

In sum, Section 4.5 is not a directive of general applicability. Its purpose is to guide agency staff in their exercise of discretion as they implement the NPDES permit program and develop site-specific discharge permits. It is not binding on either the regulated community or agency staff.

2. Enumerated categories

Because Northwest Pulp & Paper fails to show that Section 4.5 satisfies the first element of the APA’s definition of a “rule,” we decline to consider whether Section 4.5 falls into one of RCW 34.05.010(16)’s enumerated categories and satisfies the second element.

We hold Ecology did not adopt a rule when it added Section 4.5 to the Manual.

B. Northwest Pulp & Paper Has Not Established Invalidity Under the APA


Northwest Pulp & Paper argues Section 4.5 is an invalid rule under RCW 34.05.570(2)(c) because the section was added without compliance with statutory rule-making procedures, its

promulgation exceeded Ecology's authority, and it is arbitrary and capricious. Because we hold that Section 4.5 is not a rule, RCW 34.05.570(2)(c) is inapplicable, and we do not consider these arguments.

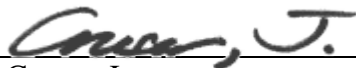
Although Section 4.5 is not subject to judicial review as a rule, we note that procedural avenues are available for dischargers to challenge an Ecology decision to impose specific requirements to test for PCBs using Method 1668C or 8082A. Dischargers may challenge the issuance, modification, or termination of their permit, including any modification of its conditions or terms, before the Pollution Control Hearings Board. RCW 43.21B.110(1)(c). Dischargers may also challenge the enforcement of any permit condition. RCW 34.05.570(3); RCW 43.21B.110(a)-(b). Additionally, requirements to use more sensitive testing methods outside of the permit's conditions, such as during the permit application process, may constitute other agency action that can be challenged under RCW 34.05.570(4).


CONCLUSION

We hold Ecology did not promulgate a rule under the APA when it added Section 4.5 to its Permit Writer's Manual. Accordingly, we affirm the superior court's order dismissing Northwest Pulp & Paper's petition for judicial review and denying its request for declaratory judgment.


Glasgow, A.C.J.

We concur:


Cruser, J.


Veljacic, J.

Appendix B



DEPARTMENT OF
ECOLOGY
State of Washington

Water Quality Program Permit Writer's Manual

Revised July 2018
Publication no. 92-109

Publication and Contact Information

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Water Quality Program Permit Writer's Manual

Prepared by:
M. Eleanor Key, P.E.

Water Quality Program
Washington State Department of Ecology
Olympia, Washington

DEPARTMENT OF ECOLOGY
Water Quality Program

July 30, 2018

TO: Ecology Wastewater Permit Writers

FROM: Heather R. Bartlett, Water Quality Program Manager

SUBJECT: June 2018 Permit Writer's Manual Update

The latest revision to the Permit Writer's Manual is attached for your use. It describes Ecology's procedures when issuing permits for wastewater discharges. Permit writers are required to use the procedures in this manual for developing permits. If a permit writer believes a permitting situation requires a different process than in the manual, the permit writer should discuss the alternative process with their supervisor. If a staff member believes a problem or issue needs to be addressed by the manual, they should recommend that their supervisor or Permit Writer's Workgroup (PWG) member bring the issue to Vince McGowan or Eleanor Key.



Heather R. Bartlett
Water Quality Program Manager

Attachment

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Note to Readers

This manual is a working document for people at the Washington State Department of Ecology (Ecology) who write wastewater discharge permits. It is available to the public on the Ecology web site at: <https://fortress.wa.gov/ecy/publications/summarypages/92109.html>.

The Department of Ecology is interested in your comments on this manual. Please address comments to:

Permit Writers Manual
Dept. of Ecology
PO Box 47696
Olympia, WA 98504-7696.

Comments may also be posted at <https://ecology.wa.gov/About-us/Get-to-know-us/Our-Programs/Water-Quality>.

Ecology permit writers will find additional resources on SharePoint at <https://partnerweb.ecy.wa.gov/sites/WQ/pwg/default.aspx> or from the Program Development Services Section.

The June 2018 update of this manual included additions to the following Chapters:

- Chapter 2, Section 16: New Permit Reauthorization Guidance
- Chapter 6, Section 3: Revised Compliance Schedule Section
- Chapter 6, Section 4: Revised PCB Guidance Section
- Chapter 6, Section 5: Revised WET Chapter Revision
- Chapter 6, Section 6: New Stormwater Section (Intro only)
- Chapter 7, Section 7: Intake Credits for Human Health Criteria
- Chapter 12, Section 1: Revised General Conditions Language
- Chapter 12, Section 3: New sections on Arsenic, Methylmercury, and DEHP Reduction

The 2015 version of the manual transitioned to a new format for figures, tables and appendices. This 2018 version continues the revised numbering approach while adding additional tables and figures. 2011 and earlier versions use a roman numeral numbering scheme. 2015 and later versions use continuous numbering of figures and tables. No changes were made to the appendices.

Chapter 1. Introduction

This manual is a technical guidance and policy manual for permit writers who develop wastewater discharge permits in Washington State. Developing this manual was specified as task element P5 in the 1987 Puget Sound Water Quality Management Plan and subsequent amendments. Maintenance and improvement of the manual is recommended in the final report of the Commission for Efficiency and Accountability in Government (1990).

The first version of this manual was issued in June, 1989. A 23-member advisory committee assisted the Department of Ecology (Ecology) for one year on policy issues identified in the manual. The advisory committee represented those interested in wastewater permits. An internal work group also assisted in the development of this manual.

The primary purposes of this manual are to enhance the quality and consistency of the wastewater discharge permits issued by Ecology and to improve the efficiency of the permitting process.

1. Objectives and Functions

The specific objectives and functions of this Permit Writer's Manual are to:

- Briefly review the legal history of wastewater permitting to provide permit writers with a perspective on their role.
- Define the requirements for permits in Washington. This manual integrates state and federal law, state and federal regulation and Ecology implementation policies. Permits reviewed for 401(a) certification must be consistent with procedures in this manual.
- Ensure statewide consistency in permitting, especially for permits which require best professional judgment (BPJ) determinations.
- Identify state and federal laws, regulations and policies relating to permitting.
- Identify legal opinions of the Attorney General's Offices, rulings of the Pollution Control Hearing Board and rulings of other courts on permitting and permit related issues.
- Gather collective knowledge of Ecology on permit writing.
- Provide a central document to place new information, guidance, and requirements related to permitting.
- Serve as a reference for experienced permit writers.
- Train new permit writers. This manual is identified in the Permit Writers Training Strategy as a component of training for new permit writers. The manual will reduce the training time for new permit writers and the demand on experienced permit writers to train new permit writers.
- Demonstrate to the regulated community and other interested public what the agency does in permitting a wastewater discharge.

This manual is a technical/philosophical compendium of experienced Ecology permit writers.

The manual is expected to be revised annually. Revisions or additions to the manual may occasionally be made between annual revisions. These revisions and additions will be sent with a transmittal cover memo from the Program Manager explaining the need for revision and where the text is to be placed in the manual.

2. Format Follows Process

The manual's format follows the process of developing a wastewater discharge permit. Because of the complexity of the permitting process it is impossible to completely separate functions chronologically. For example, the public involvement chapter is one of the later chapters in the manual because historically public involvement occurred after the permit conditions were drafted. Public involvement now begins upon permit application.

In preparing the manual, we borrowed materials freely from EPA and from other states when appropriate. These materials are cited in the reference section. They are available from the Ecology library and on the Internet.

2.1 Other References

The new permit writer should read and have on hand some reference documents related to permitting. Specifically, the permit writer should have access to water pollution laws and regulations, the Code of Federal Regulations dealing with environmental regulation (40 CFR Parts 100-149 and 400-471), and a current copy of the Clean Water Act. The permit writer should read Chapters 173-220, 173-216 WAC and study Chapter 90.48 RCW. The Technical Support Document for Water Quality-based Toxics Control (EPA 505/2-90-001) is required background reading for Chapters 6 and 7.

3. Scope

The scope of this manual includes:

- Joint State/NPDES permits as issued under Chapter 90.48 RCW and the Federal Water Pollution Control Act
- Municipal wastewater treatment plants
- Industrial/Commercial Facilities
- General Permits
- State waste discharge permits as issued under 90.48 RCW.
- Discharges to groundwater
- Discharges to municipal sanitary sewer systems as part of the state-wide (undelegated) pretreatment program.

4. Inspections and Enforcement

The issuance of a wastewater discharge permit leads to subsequent regulatory activities including inspections and enforcement. Guidance for those functions is provided in the Inspection Manual ([Ecology 92-76](#)) and the Compliance Assurance Manual (posted on the Intranet, under the Resources tab, Compliance and Enforcement).

5. Not Regulation

This manual is not regulation and should not be cited as regulatory authority for any permit condition. This manual describes law and regulation pertaining to permitting. These laws and regulations must be followed to issue a legal permit. Where those laws and regulations are not explicit on implementation the manual describes a process for implementation. This process is a program decision (policy) for implementing the laws and regulations and typically has been subject to debate by permit writers and management. If the process does not fit a permitting circumstance, the permit writer can explore alternative processes as long as the law and regulation are met. Alternative processes require section supervisor approval prior to implementation.

6. A Short History Lesson

The point source water pollution control program in this state is based on both Federal and State law which evolved concurrently. The State of Washington began a formal pollution control program in 1945 with the creation of the Pollution Control Commission and enactment of RCW 90.48. The law did not allow strong enforcement. Pollution control was a negotiation process and required the state to demonstrate a water pollution problem and assign the cause of that problem to a specific discharger.

In 1948 the federal government passed the Water Pollution Control Act (PL 80-845). This law provided some funds for the design of municipal wastewater treatment plants and for study of water pollution problems. This law also required the U.S. Surgeon General, in cooperation with the states, to develop water pollution control programs for interstate waters. The Federal Water Pollution Control Act of 1956 (PL 84-660) and its 1961 amendments (PL 87-88) established federal grants for construction of municipal treatment plants.

The Water Quality Act of 1965 (PL 89-234) required states to adopt water quality standards for interstate waters and created a small agency, the Federal Water Pollution Control Administration (FWPCA). These federal laws generally required the states or federal government to demonstrate that a water quality problem had implications for human health or violated water quality standards. Enforcement was minimal because the burden of proof lay with the agencies: they had to demonstrate a direct link between a discharge and a water quality problem before enforcing on a discharger.

Meanwhile, Washington had adopted a waste water discharge permit system in 1955 (Chapter 90.48 RCW). This permit system was apparently not very effective in controlling pollution

16. Reauthorization

A reauthorized permit is a wastewater discharge permit issued to an existing discharger that is virtually identical to the facility's expired permit. Ecology originally drafted the permit prioritization/reauthorization process to assist in reducing the number of expired permits, or backlog, in 1998. Since that time, regions have used the tool to help reduce the program's permit backlog percentage. Originally intended for minor NPDES permits and significant state permits, use of the reauthorization tool expanded over time to include major NPDES facilities and individual industrial permits. This guidance works to standardize and clarify the appropriate use of permit reauthorization for backlog reduction. Reauthorizations in this section apply to NPDES permits, only. Ecology has developed a fact sheet shell for state waste discharge permits (SWDPs) in addition to the NPDES reauthorization. While this section directly addresses NPDES reauthorizations, similar logic applies to SWDPs. Direct questions on reauthorizations to the permit QA/QC lead in the PDS Section.

Permit reauthorizations must meet requirements promulgated in 40 CFR 122 as EPA considers a permit reauthorization to be a permit issuance. The permit administrative record, permit and fact sheet addendum must demonstrate that the permit writer reviewed data supplied with the application, data collected during the previous permit term, current water quality standards, changes in receiving water status, reasonable potential analyses, and compliance history. The new permit must also contain the original fact sheet so facility information can be readily located. Permit writers must ensure the reauthorized permit and factsheet addendum provide the information needed to comply with federal regulations. Permit writers and supervisors must also understand when the reauthorization tool *should not* be utilized and instead, pursue a formal reissuance.

The determination of which permits to reauthorize and which to reissue stems from existing facility knowledge and the significance of the discharge. Previously, staff and supervisors used a permit priority ranking process for identification of reauthorization candidates. Ultimately, the decision to reauthorize rather than renew or reissue the expired permit should be made by the section supervisor.

Permit writers must determine whether the reauthorized permit conditions will be identical to the current permit. A permit may be reauthorized only if the permit writer documents no significant changes to the individual facility's permit requirements. Permits should not be re-authorized more than once before full re-issuance.

While permit reauthorizations should save permit development time, the permit writer must still review permit compliance, characterize effluent data, reassess the receiving water body for any impairments, review the appropriateness of previous effluent limits (including a reassessment of reasonable potential), and provide other necessary documentation that supports the decision to reauthorize rather than reissue a permit. Permit writers must place the permit requirements in the most recent permit shell to capture any changes to Ecology's permitting program that may have occurred since the previous issuance. Other than use of the new permit shell, the only other changes should be to submittal, effective, and expiration dates. Minor changes to monitoring schedules are acceptable. Under no circumstances can the reauthorized permit be less stringent

than the current iteration. The reauthorization fact sheet addendum must accompany the previously issued fact sheet, the reauthorized permit, and the updated coversheet complete with a new Section Manager signature.

The reauthorization addendum fact sheet template is available on the Permit Writing Resources SharePoint site along with the fact sheet and permit shells used for permit development. The addendum explains the reauthorized permit, implications of the reauthorization process, recommendations for the permit term, any changes to submittal dates, and updates to Ecology's public notice procedures. This addendum does not replace the expired permit's fact sheet as the previously issued fact sheet continues to be part of the permit record. It is imperative to keep the previous fact sheet as part of the permit record because it provides relevant facility history and the basis for permit requirements. In addition, packaging the fact sheet addendum with the previous fact sheet ensures compliance with 40 CFR 124.56.

Information required in the fact sheet addendum must include facility details, a compliance assessment, updated receiving water information (including any changes to listings), effluent characterization through the previous permit term, a discussion of reasonable potential using all new data, and a review of decisions made during the previous permit cycle related to effluent limit development. The effluent limit review discussed in the fact sheet addendum must include a revised reasonable potential analysis calculation. Permit writers must use the most recent version of PermitCalc to capture changes to water quality standards which may have occurred during the previous permit term. The revised reasonable potential analysis must use data collected during the previous permit cycle in addition to any data submitted with the application or otherwise. Results from the RPA should not change effluent limits. Failure to provide this required documentation undermines Ecology's use of reauthorization as a permitting tool.

When the following conditions exist, a discharge permit should not be reauthorized and should be reissued:

- Permit is under previous reauthorization.
- Design flows exceed 1 MGD.
- The discharge quality/quantity or production levels have significantly changed.
- A pollutant of concern is identified through the reapplication process or during the previous permit cycle.
- The facility is a known source of a pollutant to an impaired water body and reissuance will result in an overall water quality improvement due to tighter effluent limitations.
- A TMDL has been completed for the impaired receiving water and a WLA must be implemented.
- The current permit has a compliance schedule and interim (or performance based) effluent limits that must be reassessed.
- Significant changes are necessary to the compliance monitoring requirements.
- Significant concerns exist within the Agency or Public entities over current permit requirements.

- Reasonable potential exists to violate water quality standards and requires a more stringent limit based on review of the permit application and the previous permit cycle's performance data.
- Additional pretreatment requirements are necessary.
- Any permit requirement becomes less stringent.

Chapter 6. Water Quality-Based Effluent Limits for Surface Waters

Permit writers must consider the impact of every proposed discharge to surface waters on the quality of the receiving water and specifically consider how the discharge may affect the use of the receiving water. In some cases, this consideration may reveal that permit limits based on a treatment technology are not sufficiently stringent to protect water quality even with a mixing allowance. In these cases, additional permit limits must be developed, or alternative disposal methods or locations must be found. This chapter deals with conducting an analysis of reasonable potential and developing effluent limits for the protection of aquatic life for individual permits. Human health protection is covered in Chapter 7. Appendix E covers the situation where a TMDL has been developed and water quality-based effluent limits are based on a wasteload allocation set by the TMDL.

To evaluate the effect an effluent has on receiving water, a permit manager must use:

- The water quality criteria and standards described below in Section 1,
- The mixing zone criteria described below in Section 2, and
- A method for predicting impact and defining effluent limits for numeric criteria described below in Section 3.

The permit writer should keep in mind that the requirement for imposing effluent limitations for the protection of water quality does not require a demonstration of impact beyond any doubt but only that there is a determination of reasonable potential determined by a rational and scientific process.

Section 4 of this Chapter describes analytical levels for permit application and effluent limits.

Evaluating an effluent's effect on receiving water includes an evaluation of whole effluent toxicity (WET). Section 5 presents Ecology's approach for dealing with whole effluent toxicity.

Additional guidance on determining effluent mixing is presented in Appendix C.

1. Water Quality Criteria and Standards

Water quality criteria are estimated threshold concentrations for specific pollutants which are based on scientific data about adverse effects to aquatic life or human health. These criteria address human health effects, toxicity to aquatic organisms, bioaccumulation potential, or an adverse effect on some other beneficial water use. These criteria may be single numbers, a concentration range, or a narrative statement.

The first water quality criteria developed by direction of the Water Quality Act of 1965 and the Federal Water Pollution Control Act (Clean Water Act) have since been revised several times.

The methods used for deriving the criteria have changed over the years. The different methods

Hardness, pH, and temperature which affect the numeric criteria for some metals and ammonia will also vary seasonally and must be accounted for in setting limits. The information on these variables should be developed by the permittee. The permit writer should also consider the difficulty of accounting for upstream dischargers if there are multiple dischargers to a reach. Where conditions become too complex to authorize flow adjusted limitations, the permit writer should consider doing static water quality-based limits and authorizing a compliance schedule to incorporate the time necessary to do the TMDL.

4. Analytical Levels

This part discusses detection and quantitation levels and outlines an approach to assess compliance with water quality standards and with effluent limits that are near or below the levels of quantitation. The approach is primarily for organic and metal pollutants where criteria and effluent limits may be very low. Chemical-specific concentration levels that can be used for compliance assessment are presented, as well as guidance on how to tailor those levels to fit regulatory concerns regarding the possible impacts of the discharge. Compliance levels are expected to change over time as analytical methods improve and as we gather more data on laboratory performance.

For NPDES permits, the permit writer must require EPA Methods as given in 40 CFR Part 136 (see: <https://www.epa.gov/cwa-methods>) and specify the specific method to achieve detection and quantitation levels for permit application or permit compliance monitoring. If a test method is not listed in part 136 for a permitted pollutant then the permit must specify an appropriate test method [40 CFR Part 122.44(i)(1)(iv)].

One group of compounds where analytical methods are evolving rapidly are Polychlorinated Biphenyls (PCBs). Additional guidance on this group of compounds is found later in this section.

4.1 Introduction

Effluent limits based on water quality criteria may be set at very low concentrations (in the range of parts per billion to parts per quadrillion). Laboratory analytical methods approved for use in the NPDES program are often not capable of measuring chemical concentrations at the concentrations of the permit limits. In many cases we are unable to determine if pollutants contained in discharges are at concentrations that merit concern, and when we set an effluent limit, we are often unable to determine if that limit is being exceeded.

Historically, the **method detection limit (MDL)** was used to determine compliance (all data at or above the MDL were considered adequate for assessing compliance and supporting enforcement actions). The MDL, however, is the level at which a chemical's presence or absence can be detected, and provides limited information with regard to actual concentration. The low concentrations of many of the aquatic life-based and human health-based criteria have made the issue of quantitation important to both the regulator and the discharger. This section uses the term “**quantitation level**” as equivalent to the term “**minimum level of quantitation (ML)**” which is used by EPA. The ML is defined by EPA as the lowest concentration of an analyte that

Table 14. Methods, Detection and Quantitation Levels Recommended for Effluent Characterization and Effluent Monitoring

Pollutant & CAS No. (if available)	Recommended Analytical Protocol	Detection (DL) ¹ µg/L unless specified	Quantitation Level (QL) ² µg/L unless specified
Conventionals			
Biochemical Oxygen Demand	SM5210-B		2 mg/L
Chemical Oxygen Demand	SM5220-D		10 mg/L
Total Organic Carbon	SM5310-B/C/D		1 mg/L
Total Suspended Solids	SM2540-D		5 mg/L
Total Ammonia (as N)	SM4500-NH3-B and C/D/E/G/H		20

1. **Detection level (DL)** or detection limit means the minimum concentration of an analyte (substance) that can be measured and reported with a 99% confidence that the analyte concentration is greater than zero as determined by the procedure given in 40 CFR part 136, Appendix B.
2. **Quantitation Level (QL)** also known as Minimum Level of Quantitation (ML) – The lowest level at which the entire analytical system must give a recognizable signal and acceptable calibration point for the analyte. It is equivalent to the concentration of the lowest calibration standard, assuming that all method-specified sample weights, volumes, and cleanup procedures have been employed. The QL is calculated by multiplying the MDL by 3.18 and rounding the result to the number nearest to $(1,2,\text{or } 5) \times 10^n$, where n is an integer. (64 FR 30417).

ALSO GIVEN AS:

The smallest detectable concentration of analyte greater than the Detection Limit (DL) where the accuracy (precision & bias) achieves the objectives of the intended purpose. (Report of the Federal Advisory Committee on Detection and Quantitation Approaches and Uses in Clean Water Act Programs Submitted to the US Environmental Protection Agency December 2007).

4.5 Polychlorinated Biphenyls (PCBs)

PCBs are a persistent, bioaccumulative, and toxic group of manmade compounds found throughout the environment. Federal NPDES permitting regulations require use of analytical test methods approved under 40 CFR Part 136 for assessing compliance with permit limits. The method currently approved for use in PCB analysis under 40 CFR Part 136 is Method 608. Method 608.3, released in December 2016, contains updates for PCBs; however, this method was not published in the Federal Register prior to the change in Executive Administration in January 2017. As is common with new Administrations, Federal Agencies issued a mandatory recall of all actions that were not published in the Federal Register prior to the Administrative change. The final rule was published in August 2017. After the delayed publication, Method 608.3 became the preferred method by Ecology for effluent limit compliance evaluation; however, laboratories have one year to comply with this revised method due to the MDL development procedural changes. Through August 2018, laboratories may still use modified Method 608 for compliance if they have not yet received accreditation for Method 608.3. See 4.5.1 in this chapter for detail on using modified 608 for effluent limit compliance.

As of January 2017, the three methods that are used for permitting purposes are Methods 608, Method 8082A (Update V) and Method 1668C. Methods 8082A and 1668C are not-EPA approved methods under 40 CFR 136. Recent EPA revisions to 608.3 and 8082A refine QA processes and increase method sensitivity. Method 608 (or 608.3) and [Method 8082A](#) are methods for reporting Aroclor concentrations (7 individual Aroclors). Method 8082A can also report some congeners. [Method 1668C](#) is a very sensitive method for reporting congener

concentrations (209 individual congeners). All three methods sum the results (Aroclors or congeners) to calculate a total PCB concentration. Surface water regulatory standards for chronic aquatic life and human health criteria are set at levels lower than EPA Method 608 (or 608.3) are able to evaluate. The two other methods used to evaluate PCBs, 8082A and 1668C, provide lower analytical limits and may be used for permitting purposes to evaluate sources, but not for numeric effluent limit compliance. Section 4.5.5, Table 18, gives a comparison of the different reporting limits for all methods discussed in this chapter.

4.5.1 Method 608

In response to a Pollution Control Hearings Board decision (Case Number P13-137c) in July 2015, Ecology conducted a phone survey of over 20 labs in Washington to determine achievable detection levels (DLs) and quantitation levels (QLs) for water samples under Methods 608 and 8082A. Labs indicated that DLs and QLs lower than required by Ecology in NPDES permits were achievable with modifications to both methods. Common techniques were reported to lower detection limits: extracting a larger than one liter sample, large volume injection, concentrating the sample extract, and solid phase extraction (SPE). But the relatively high QL for 608 was problematic and bound by the strict requirement that the method-specific standard deviations (e.g., calibration factor or response factor) be less than ten percent for the calibration curve of each Aroclor. Also, some techniques like SPE were allowed with 8082A but not with 608.

Recently, EPA promulgated the [Methods Update Rule](#) (December 2016) that includes Method 608.3 for PCB Aroclor determination. This update was recorded into the Federal Register in August 2017 and recognizes advancements in laboratory techniques and technology that were identified by local labs. Specifically, the new method includes more techniques for extraction and clean-up, revised MDL determination procedures to account for lab blank contamination, and sets the calibration curve to twenty five percent standard deviation. Extraction techniques such as separatory funnel, continuous liquid-liquid for extraction and SPE are now included. These modifications have prompted updates to lab standard operating procedures (SOPs), and labs have worked with Ecology's Laboratory Accreditation Unit (LAU) for accreditation beginning August 2017 for NPDES permit requiring analysis using Method 608.3. LAU has granted accredited laboratories a compliance period of one year so that they may implement the new MDL procedures. The end of this compliance period is expected to occur in September 2018. In the interim, laboratories accredited for Method 608 may use the modified procedures discussed earlier in this section to increase the methods sensitivity.

Permit writers must work with permittees to ensure they use the 2016 update for Method 608.3 in NPDES permits as soon as their associated laboratory becomes accredited. This may occur before September 2018. The update sets the DL at 0.065 µg/L and the QL at 0.195 µg/L (3x the DL). These reporting limits apply to all Aroclors even though it is only specified for PCB-1242 in the method. Laboratories may use Aroclor 1242 as an indicator for determination of the method validation statistics. Language in the method states: *“When analyzing the PCBs as Aroclors, it is only necessary to establish an MDL for one of the multi-component analysis (e.g., PCB 1254), or the mixture of Aroclors 1016 and 1260 may be used to establish MDLs for all of the Aroclors”* (EPA, Method 608.3). The method QL revision in Method 608.3 results from a change in the tolerance for the relative standard deviation from 10% to 20% (for external

standard calibrations) and 15% (for internal standard calibration). Permit managers should verify the laboratories QA/QC report supplied with analytical results against both the reporting limits in Appendix A and also Table 4 of the EPA published method text. If there are questions related to laboratory quality assurance verification, contact LAU or someone else at Ecology that has experience in interpreting laboratory data. *NOTE: Table 2 of published method 608.3 erroneously reports the QL for Aroclor 1242. The correct value is 0.195 ug/L, not 0.095 ug/L as recorded.*

Permit writers may consider lower QLs for a permit only if laboratories can demonstrate quality assurance using Method 608.3 procedures for samples from highly treated wastewater or other discharges with relatively low levels of pollutants. This is due to less potential for matrix interference. If electing to modify the DL and QL, Appendix A should reflect that change. It is the permittee’s responsibility to ensure the laboratory can meet the change in the method validation statistics.

The lower DL and QL level achievable with Method 608.3, may lead to an increase in qualified data (estimated values reported below the QL, but above the DL) in lab reports. See Section S3 Reporting and Recording Requirements for an explanation of how Permittees must report data qualifiers in WQWebDMR. In addition, fact sheets must provide a description of how Ecology uses qualified data in the permit data summary and subsequent reasonable potential analyses. See Section 4.3 of this chapter for a description of how to use analytical results that fall between the DL and QL in permitting. Part IV of the fact sheet shells also contains optional language handling qualified data when effluent limits are near detection or quantitation levels. This language should be used and modified, if necessary, for the specific permitting situation.

Method 608 must be used for permit compliance until a laboratory used by a permittee becomes accredited for Method 608.3. Lowering the DL and QL for Method 608 through refinement of laboratory procedures does not affect the method’s approval for permit compliance. Table 15 lists both the unrevised and revised DLs and QLs for Method 608 Ecology used for permitting prior to promulgation of Method 608.3. See Appendix A for the most up to date reporting limits for PCBs as defined in Method 608.3. Table 18, later in this chapter, lists reporting limits for all three PCB analytical methods discussed in this chapter.

Table 15. Method 608 Limits of Reporting prior to 608.3

EPA Method	DL, µg/L	QL, µg/L
608 (unrevised)	0.25	0.5
608 (revised)	0.05	0.2

Laboratories electing to use the Method 608 revisions must update their SOPs for the change in analytical technique. Once updated, the LAU must conduct a review prior to the laboratory running analyses for NPDES permit compliance. Labs are responsible for contacting LAU to verify what is needed for receiving approval to run the revised Method 608 procedure. Initial documentation for this method revision at a minimum must include: acceptable proficiency testing (PT) sample results, initial demonstration of capability (IDC) with an alternative source

standard (see Section 8.2 of Method 608), a MDL summary, and a calibration curve showing acceptable quality control.

Permit writers need to notify Permittees if requiring use of the revised Method 608 during permit development. An explanation regarding the requirement of the revised method should also be provided in the Fact Sheet. **Note that after September 2018, the appropriate compliance method is 608.3.** Laboratories transitioning to Method 608.3 are responsible for contacting LAU to verify what is needed for accreditation. When effluent concentrations fall below the DL and QL of Method 608-revised, or Method 608.3, and the permit writer has reason to suspect PCB contamination, the permit writer should consider a characterization monitoring requirement using Methods 8082A and/or 1668C discussed in Sections 4.5.2 and 4.5.3 of this chapter. In the event of an EPA-approved TMDL that assigns numeric wasteload allocations, permits must require monitoring using Method 608.3 to assess compliance with the wasteload allocation assigned to the discharge. In this instance, for example, there is no need for characterization monitoring using a more sensitive method because PCB loading in the discharge has already been quantified. Other methods for other purposes, such as source control and adaptive management, may still be necessary. In general, discharges from small municipal facilities do not need characterization monitoring as there is little risk of direct PCB inputs to the collection system. Permit writers should still consider potential site specific information for these small dischargers and use best professional judgement when developing monitoring requirements. See Section 4.5.5 of this Chapter for additional discussion.

4.5.2 Method 8082A

In August 2015, EPA promulgated ‘Update V’ to SW-846 Methods, including an update to the organic compound series - 8000D Determinative Chromatographic Separations, which includes Method 8082A. Ecology’s LAU will begin to accredit labs related to Update V during routine on-site audits beginning in January 2017.

Key features of Update V for Ecology’s NPDES program are the steps taken to improve the quality assurance of the laboratory data, particularly reduction to a single limit for reporting. Chapter One of SW-846 defines the Lower Level of Quantitation (LLOQ) as: The lowest point of quantitation which, in most cases, is the lowest concentration in the calibration curve. Update V now requires laboratories to only report the LLOQ (no QL or DL), which is a function of both the method and the sample being evaluated.

Previously the DL only considered the blank spike which often resulted in unachievable MDLs for complex matrices such as stormwater or process wastewater. The LLOQ considers the effect of sample matrix throughout the entire analytical process for a batch of samples. Therefore, it is better suited for samples with complex matrices (e.g., process wastewater and solids). Results above the LLOQ are quantifiable within acceptable precision and bias, and are reported with a known level of confidence. The LLOQ is verified periodically with laboratory control samples (blank spikes), using lab-specific statistically based recovery limits or project limits. The new QC protocol for this method requires validation to the lowest point on the calibration curve developed by the individual laboratory. LAU is available to answer questions regarding LLOQ requirements if permit writers have specific questions during permit development, developing Quality Assurance Project Plan requirements, or when interpreting laboratory reports.

As a performance-based method with a single reporting limit, laboratories now have more flexibility with sample preparation. These modifications provide more trust in the analytical data as it results in fewer qualifications due to a necessary increase in accuracy and precision. In 2015, just prior to Update V (using 8000C), local labs using Method 8082A reported they consistently achieved DLs of 0.008 µg/L and reporting limits of 0.016 µg/L in most samples using routine extraction and clean-up techniques such as continuous liquid-liquid or solid phase extraction (SPE).

Starting in 2017, Ecology expects laboratories to update method SOPs for accreditation of the 8082A –Update V. While waiting on laboratory accreditation through LAU, permit writers may consider using both an LLOQ set to 0.016 µg/L and variable DL dependent on the quality of the individual discharge. Samples from highly treated wastewater or other discharges with relatively low levels of pollutants are more likely to pass the LLOQ quality assurance due to less potential for matrix interferences. Permit writers may consider lower LLOQs using Update V Method 8082A procedures for a permit only if the laboratory can demonstrate quality assurance in those samples.

Whether a lab will report on qualified data (data between the DL and LLOQ) is a decision made by each lab, project or permit. Ecology understands that laboratories may report both a DL and LLOQ for a period of time while labs become accredited under Update V. Until accreditation is reached, permit writers must specify both the DL and LLOQ for the method, not just the LLOQ, and verify reporting limits in the lab report received provided with the results. When specifying the DL in addition to the LLOQ, permit writers should work with the appropriate laboratory to ensure the reporting limits are sensitive enough for the site specific analysis. Permittees can continue to request laboratories to use the dual reporting method even after receiving accreditation for Update V. Permit writers should use their judgement on requiring the dual reporting method. In general, the change to the single reporting method is considered to be an important improvement. Use of the LLOQ supports the Water Quality Program’s need for Permittees to generate verifiable data while meeting necessary precision and accuracy thresholds for source identification, source control, discharge characterization and other required monitoring.

Qualified data (estimated values reported above the DL and below the LLOQ) is anticipated to decrease in frequency as labs are accredited for 8082A-Update V and move to the single reporting limit. Method quality objectives (MQOs) for Update V should only be used once a laboratory has become accredited for the revision. See Section 4.5.4 for a discussion on MQOs and sampling plan development.

Permit writers should specify the LLOQ for the compliance assessment level and include footnotes explaining the monitoring requirement in S2. In addition, the permit writer needs to clearly state how qualified data (below the LLOQ) will be used. If the permit contains a requirement for monitoring PCBs using Method 8082A and the dual reporting method is used, follow procedures in 4.3 of this section, replacing QL with LLOQ, for calculating averages and other statistics. After becoming accredited for Update V, the procedure listed in Section 4.3 still applies; however, laboratories will flag results that fall below the LLOQ and are unlikely to

return a numeric result. Data below the LLOQ should not be used in calculating averages as it lacks a level of certainty that the analyte is in the sample.

The permit should provide clear direction about how to report data qualifiers in PARIS if requiring the data be submitted with a DMR. Alternatively, the permit writer has the option of requiring the data to be submitted separately from a DMR. Regardless, the fact sheet should provide a full description of how Ecology will use (or disregard) qualified data. This becomes especially important when permit writers use qualified data in calculating or evaluating numeric limits. Some source identification activities may adjust how qualified data is used and this should also be well described in the permit, fact sheet and PARIS. The method modification to a single reporting limit (LLOQ) should help to reduce qualified data as reported by the laboratory.

A permit writer should require MQOs for Method 8082A in permits based on necessary performance measures needed for the specific monitoring event. In some permits, permit writers may require the Permittee to develop a QAPP to provide more information for the data evaluation procedures. If using Method 8082A, a QAPP is recommended as a permit requirement especially if requiring dual reporting limits. Use of a QAPP will implement reporting limit requirements for laboratories so that data collected by permittees is properly quantified and qualified for permitting decisions and data quality objectives. Ecology has QAPP templates which are available to both permit writers and permittees. See Section 4.5.4 for an example of MQOs to be provided in a QAPP for 8082A Update V analyses, which must be modified based on project specific needs. Analytical laboratories should be contacted for input regarding the MQOs for the analysis prior to QAPP finalization.

Permit writers still need to evaluate the percentage of qualified data in the laboratory report, especially in the instance when laboratories have not been accredited for Update V. When data qualifiers or ND values start to exceed a 25% threshold, permit writers should apply their best professional judgement and consider utilization of Method 1668C. An instance where more sensitive monitoring may not be required is when PCB concentrations start to fall after successful installation and management of BMPs. Best professional judgement must be applied and explained in the fact sheet in this situation.

4.5.3 Method 1668

Method 1668c is a very sensitive analytical method that has the capability of detecting 209 different PCB congeners. Water quality standards are based on Total PCBs (the sum of all Aroclors, isomers, homologs, or congeners), and have most frequently been measured as a calculated sum of all or a select group of congeners (e.g. a grouping representing an Aroclor) found in a sample. The data generated by Method 1668C is more complex and extensive than data generated by the other two methods, and must be carefully managed, assessed and applied. As of 2018, PARIS is not equipped to handle analytical results from Method 1668C due to method complexity. This data must be required as part of a separate submittal or report. Raw data files from these analyses should be filed as part of the permit record and associated with the specific submittal number in PARIS.

The process to interpret lab data and evaluate usability of data produced by Method 1668C toward permit needs should be spelled out in a Quality Assurance Project Plan (QAPP). See

Section 4.5.4 for a discussion on QAPP development considerations. Based on expertise from elsewhere in the U.S. (e.g. Delaware River Basin PCB Monitoring), additional data management standard operating procedures that explicitly deal with analytical method QA/QC, column types, blank contamination, raw vs. censored data, matrix interference, and co-eluting PCB congeners are needed to allow for consistent use of PCB congener data in permits.

When conducting sampling for analysis using Method 1668C, the permittee must submit a QAPP for approval as site specific requirements will determine measurement quality objectives (MQOs). A permit related QAPP will document a consistent manner with respect to procedures (e.g. interpreting lab control samples, blank censoring, calculating total PCBs) specific to the level of certainty required in decision-making. Data produced from this method could be used as the basis for developing effluent limits, to measure attainment of water quality standards, and other critical measures (see section below), therefore, the QA/QC must be rigorous. It is recommended to follow data qualifiers used by Manchester Environmental Lab for consistency during the quality assurance process. This helps to eliminate confusion related to labs using custom qualifiers with differing definitions.

As a rule, any Method 1668C analysis should include both field and laboratory blanks in the required sample sets as a way to increase result precision. Permit writers should never use raw data generated in a Method 1668C analysis for congener summation. When PCB concentrations are very low, background contamination in lab or field blanks may interfere with the calculation of total PCB. For reference, equipment or field blanks are sample containers filled with distilled water and are used to determine contamination from glassware, any preservatives used, or from ambient field conditions. Laboratory blanks, or method blanks, are used by the laboratory to ensure no contamination occurs at any point during the analytical procedure. Labs also use these blanks as part of their quality assurance procedure. Comparison of the field and laboratory blanks is useful in determining a source, if any, of sample contamination. As an example, MDLs for Method 1668C can range from 7 – 50 pg/L in water (depending on matrix interferences). For reference, levels of PCBs in laboratory blanks using highly distilled laboratory water (e.g., ‘nanopure’ or ‘Milli-Q’) can be as high as 50 pg/L. Permit writers should generally expect to see blank contamination in analytical results when using Method 1668C. It is important to know how to evaluate data after confirming blank contamination.

A common technique to deal with blank contamination is called censoring and is described in EPA's National Functional Guidelines for the Contract Laboratory Program. These guidelines recommend censoring congeners (not including them in the calculation of total PCBs) if they are in the sample at a concentration of less than 10x the concentration found in the *laboratory* blank. Each sample set should have both a field and laboratory blank for censoring purposes. Using 10x censoring for summation of the 209 PCB congeners removes false positives that are not significantly above (e.g. less than 2 standard deviations from the mean) the blank level. The value of 10x equates to 95% confidence level that the congener is present in the sample and is also quantifiable. For the purposes of developing effluent limits, the process of applying the 10x laboratory blank censor is appropriate. Utilizing a blank censoring procedure becomes important in low concentration scenarios and does not need to be applied to results reporting high congener concentrations. Note, if results show higher concentrations where blank contamination has little effect on the data analysis, permit writers should confirm that 1668C is the most appropriate

method. A less sensitive method may be appropriate in this instance. Overall, the choice of a censoring technique and factor (e.g. 3x, 5x or 10x) is specific to data, project needs, and the study objective. For comparison, blank censoring at 3x or 5x is used for identification of sources and can be a semi-quantitative analysis that may yield false positives which prevents it from being useful for the purpose of determining reasonable potential. The censoring technique and selected factor must be defined in the approved QAPP. Defining these techniques becomes part of the study's MQO and should be determined early on in the project phase. Table 16 provides an example of the blank censoring procedure.

Table 16. Method 1668C Blank Censoring Procedure

Congener	Ambient Sample, pg/L	Ambient Qualifier	Qualifier Correction, pg/L	Lab Blank, pg/L	Blank Qualifier	Qualifier Correction pg/L	10x Censor pg/L
PCB-001	2.04		2.04	1.37	J	1.37	0
PCB-002	1.65	J	1.65	0.537	NJ J	0	1.65
PCB-003	2.27		2.27	1.14	NJ J	0	2.27
PCB-004	8.82		8.82	1.33	UJ	0	8.82
PCB-005	0.802	UJ	0	1.03	UJ	0	0
PCB-006	2.05		2.05	0.91	UJ	0	2.05
PCB-007	1.06	NJ J	0	0.938	UJ	0	0
PCB-008	6.35		6.35	1.09	J	1.09	0
PCB-009	0.943	NJ J	0	0.913	UJ	0	0
PCB-010	0.691	UJ	0	0.886	UJ	0	0
PCB-011	44.4		44.4	4.36		4.36	44.4
Sum:							59.2

*Note: U, NJ, and UJ qualifiers set at zero

Method 1668C is not currently approved by EPA for effluent limit compliance under 40 CFR Part 136. And, Ecology is *not* proposing to seek EPA approval of this method under 40 CFR 136.5 as there are known problems in regards to the repeatability and accuracy of the method in addition to the expense of the analysis. Permit writers should continue to use the most sensitive methods approved by EPA for compliance with numeric effluent limits, which is Method 608.3. As previously stated, Ecology's permitting database (e.g., PARIS) is not yet modified to reflect such standardizations for effluent PCB congener data. EIM, the environmental database, does contain some receiving water information from studies initiated by both the Water Quality and Environmental Assessment Programs. If interested in data within EIM, permit writers must contact the appropriate project manager before using the results in any part of the permitting process. Often times, the associated laboratory blank results are not included with site specific data in EIM or the database contains previously censored data. Both sets of results from the raw sample data and the laboratory blank are necessary for evaluation purposes. With permit required sampling, permit writers should also request raw data from the analytical laboratory even if the QAPP requires blank censoring as part of the procedure. There may be times when permit writers may want to evaluate PCBs for specific congener patterns at a more refined level or with a different blank censor. All raw data should be maintained as part of the permit record.

This section will be modified following development of a standardized procedure for storing PCB congener data in an Ecology environmental database.

Ecology recognizes many situations where targeted monitoring under Method 1668C is useful for identifying PCB sources or characterizing media of interest for use in assessments other than compliance with a numeric effluent limit (such as evaluating the effectiveness of a best management practice). The following section provides guidance on QAPP development and subsequent use of this data.

4.5.4 Data quality in low level methods

Permit writers should consider the following guidance when requiring monitoring using either method 8082A or 1668C.

The way to ensure characterization or source control monitoring returns viable results is to require a Quality Assurance Project Plan (QAPP) as a permit submittal. QAPPs are not generally required for effluent limit compliance monitoring as the methods approved by EPA (e.g., 608.3 for PCBs) contain specific tolerances and acceptance criteria. Rather, QAPPs should be required when permits require additional monitoring using Methods 8082A or 1668C. See 4.5.2 and 4.5.3 for a discussion of these methods and reporting requirements.

QAPPs document and outline the planning necessary for the collection and subsequent analysis of environmental data. Approved QAPPs ensure that the collected environmental data can be used for making decisions including BMP effectiveness or delineation of specific sources. Ecology has several examples of completed QAPPs for PCB analysis and also a [QAPP template](#) that the permittee can follow. The Environmental Assessment Program is a good resource if permit writers have questions regarding required QAPP elements. The responsibility of QAPP development falls on the permittee, not the permit manager, when the discharge permit contains the specific monitoring requirement. However, the permit manager must consult with the regional QA authority who may be in another program or WQ-PDS QA authority after receiving a completed QAPP. QAPP approval must come from the appropriate QA authority and not the permit manager. There may be times when the permit manager must develop a QAPP in conjunction with another program. The rest of this section will help to explain the QAPP development process.

The permit manager and permittee must understand the purpose of data collection, or the end use goal, because it may affect the data management procedures including statistical evaluations conducted on the analytical results. The data validation step following sample collection and analysis ensures results are usable to satisfy project objectives. Study objectives include determination of initial method target levels and the intended use of the final product. Essentially, successful study objectives involve knowing the question the additional monitoring is going to attempt to answer and what kind of data is needed to meet that end. When determining study objectives, permit writers should think about the problem statement. What are you trying to do? Making a decision verses estimating a problem are two examples of different study objectives. For example, when trying to find sources within a site, individual congener profiles may be necessary to identify contaminant specific signatures that can be used to pinpoint the origin of contamination.

Permit writers should work with permittees so that the QAPP's data quality objectives (DQOs)

satisfy specific project needs. The stepwise DQO development process follows these functions with the QAPP satisfying the last step of the process:

1. Determine the problem.
2. Identify the project endpoint and/or goal.
3. Identify information needed to reach the endpoint.
4. Define the scope of the project.
5. Determine the analytical approach necessary to meet the project.
6. Set measurement quality objectives.
7. Prepare a plan for data collection and analysis (QAPP).

Effective QAPPs cover both quality control and quality assurance for the sampling event and subsequent data analysis. Quality control (QC) and quality assurance (QA) are not the same; although, some use the terms interchangeably. It is important to distinguish between the two as they represent portions of the study design and analysis. The process of data collection, management and subsequent analysis fall under QC. Development of a standard operating procedure (SOP) for the field collection and analytical laboratory is QA. The SOP provides details on how to evaluate and control data accuracy. When utilizing low level PCB analytical methods for effluent characterization or source evaluation, permit writers need to determine specific method performance criteria otherwise known as measurement quality objectives (MQOs). These MQOs must be part of the approved QAPP. For context, MQOs relate to the acceptance threshold for data. Data quality indicators (DQI) form the basis of an MQO and directly link both laboratory instrument and analytical performance forming the primary data validation criteria. Primary DQIs represent the following: precision, bias, sensitivity, representativeness, completeness, and comparability. The following offers examples and considerations when developing DQIs:

- **Precision:** Are field and/or lab duplicates necessary?
- **Bias (Accuracy):** Are method (lab) blanks necessary to quantify laboratory contamination? What are the requirements for measuring both blank and matrix spikes? Both of these involve intentional dosing with a known concentration of the analyte of interest. This known concentration is used to evaluate the percent recovery for purposes of ensuring the analytical procedure meets specific method controls.
- **Representativeness:** Do the sampling locations represent site conditions?
- **Completeness:** How much data is necessary to meet project objectives? What is necessary for the laboratory to conduct data validation?
- **Comparability:** Are units comparable? What about methods or specific qualifiers if using different laboratories?
- **Sensitivity:** Make sure reporting limits are sufficient for the study objectives.

Table 17 provides an example of MQOs for water samples to quantify PCBs by Method 8082A, Update V. Contents of the table must be verified with both the lab prior to analysis and the appropriate agency QA authority.

Table 17. Laboratory MQOs for water samples to quantify PCBs by Method 8082A, Update V

QC Element	Performance Measure	Water samples for PCBs by EPA Method 8082A; Update V
Lowest Level of Quantitation (Reporting Limit)	Sensitivity	0.016 ug/L
Field Replicate (Split Sample)	Representativeness, Accuracy	RPD \leq 40%
Analytical (Laboratory) Replicate	Bias and Precision	Compound specific RPD < 40%
Method Blank	Bias	Analyte concentration <MDL; if \geq MDL, lowest analyte concentration must be \geq 10x method blank concentration
Laboratory Control Sample / Certified or Standard Reference Material	Bias and Accuracy	50-150 % recovery
Matrix Spike and Duplicate RPD	Bias and Accuracy	50-150 % recovery; \leq 40 R RPD
Surrogate Spike	Bias and Accuracy	Compound specific; within 25-150 % recovery

[1] = for laboratories not yet accredited by Ecology for Method 8082A Update V for LLOQ, default to the reporting limit or quantitation limit of 0.016 ug/L

LLOQ vs RL: The LLOQ

RPD: relative percent difference. RSD: relative standard deviation. MDL: method detection limit.

Analytical Replicates: Provide precision information on the actual samples; useful in assessing potential samples heterogeneity and matrix effects.

Method blank for water samples: Laboratory blanks are used for instrument calibrations and determining whether any contamination is present in laboratory handling and processing of samples. Method blanks are prepared in the laboratory using the same reagents, solvents, glassware, and equipment as the field samples.

Laboratory Control Samples: Sometimes called check standards or laboratory control samples, are method blanks spiked with surrogate compounds and analytes; useful in verifying acceptable method performance prior to and during routine analysis of samples.

Surrogate Spike Compounds: A type of check standard that is added to each sample in a known amount prior to extraction or purging.

Matrix spikes and matrix spike duplicates: A matrix spike provides a measure of the recovery efficiency and accuracy for the analytical methods being used under the same conditions as the field sample. A separate container of the field sample is needed to evaluate a matrix spike sample. Matrix spikes duplicates are used to determine method accuracy and precision. Common notation is matrix spike/matrix spike duplicate [ms/msd].

Matrix Spikes: Percent recoveries of matrix spikes are reported and should include a wide range of representative analyte types; compounds should be spiked about 5x the concentration of compounds in the sample or 5x the quantification limit.

Surrogate standards: Surrogate standards are added before extraction to monitor the efficiency of the extraction methods.

Standard Reference Materials (SRM): A material or substance whose property values are sufficiently well established to be used for calibration of an apparatus, the assessment of a measurement method, or for assigning values to materials.

Certified Reference Material (CRM): A reference material, provided by standard setting organizations (e.g., NIST, CRM), accompanied by or traceable to a certificate or other documentation that is issued by a certifying body.

Final QAPP elements document the required laboratory analysis QA procedures following the data collection phase. These procedures assess whether or not the collected data meets the specified DQIs in addition to the specific study objective. QA procedures include verification of sampling procedures, data verification and validation, in addition to determining the usability of data collected. Without QA, the data from the study cannot be used to inform the project specific questions related to the sampling event. Also, determining the DQOs prior to implementing a monitoring requirement for a source identification study or pollutant minimization plan can help maintain the cost effectiveness of a study, especially with multiple sampling events spanning several years.

When requiring characterization monitoring, it is important to consider the result you want to achieve and the appropriateness of additional sampling. These listed factors contribute to the selection of an appropriate monitoring method. Information collected through previous monitoring should help the permit writer understand which method to select. Cost of PCB analysis differs substantially from method to method with 608.3 being the least expensive and 1668C the most expensive. The difference lies in the rigorous QC processes for 1668C including the level of reporting. While 1668C will return information down to the lowest quantifiable level, it is not necessarily appropriate to require this method when method 8082A will also return detectable concentrations. The following section provides information to help determine which method is appropriate in your permit.

4.5.5 Selecting the appropriate analytical method

Before requiring any monitoring for PCBs other than priority pollutant scans, permit writers should evaluate their facility and the potential for exceeding the water quality standard. For example, small municipalities with no significant industrial users and without a legacy industry may not have PCBs in their effluent at levels that would likely exceed water quality standards. Therefore, PCB monitoring may not be necessary. This is an acceptable situation. Only include monitoring requirements when necessary for the facility and its specific discharge situation.

Data quality objectives (DQOs) should always be considered prior to placing low level monitoring requirements in a permit for purposes of characterization or source identification. Permit writers should consider the size of the facility, presence of any significant industrial dischargers, legacy source potential, the source and characteristic of the wastewater including pollutants that are or have potential to be discharged from the facility, and the result being achieved with the additional monitoring before requiring PCB characterization in permits. When in doubt, staff should consult with the permitting QA/QC lead inside the program who is familiar with permitting and monitoring challenges associated with this ubiquitous toxicant.

Understanding the potential use of collected data and which method is best suited for the required monitoring are both important considerations. Knowing the distinction between evaluating compliance with numeric effluent limits versus evaluating overall permit compliance is also necessary. While non 40 CFR part 136 methods cannot be used to evaluate numeric effluent limit compliance, a missed sampling event or late submittal of monitoring results from a non 40 CFR part 136 method constitutes an overall permit violation subject to enforcement. The following provides background to help permit writers understand both when and how to use the different methods for permit development, permit management, compliance and assessments.

Permit writers should consult Table 18 for an approximate range of reporting limits for PCB analytical methods. Reporting limits in Table 18 are to be used as general guidance in method selection. Actual reporting limits will depend on the lab performance and sample matrix. The laboratory must be contacted to verify the actual level of reporting achievable for the individual analytical method and sample matrix.

Table 18. Comparison of Reporting Limits for PCB Analytical Methods

EPA Method	DL, µg/L	QL, µg/L
608 (unrevised)	0.25	0.5
608 (revised)	0.05	0.2
608.3	0.065	0.195
8082A (LLOQ)	0.016	
1668C	0.00005	0.00007

As discussed previously, numerical effluent limit compliance must be evaluated using Method 608.3. When conducting monitoring for characterization or source control, the permit writer needs to determine a sufficiently sensitive method that will generate the most unqualified, usable data. The magnitude of PCB contamination differs across the state and can generally be attributed to historical industrial uses and atmospheric deposition. Therefore, effluent characterization and source control methods will differ based on site conditions, the type of facility (e.g. industrial or municipal), and the approximate concentration of contamination expected in the field.

It may not be necessary to have every permitted discharger enter into a characterization or source identification study. For example, minor dischargers (<1 MGD) do not need to complete priority pollutant scans and often have little to no effluent toxics data. This is because minor dischargers are not subject to the same federal regulations as major or industrial dischargers. While PCB monitoring may be appropriate for some dischargers based on individual facility characteristics, permit writers should consider the value and purpose of requiring PCB monitoring when developing discharge permits. If you received NDs on the Method 608.3 analysis, consider site specific needs. Low level PCB monitoring should only be used when working to identify sources or differing magnitudes of contamination.

Evaluating reasonable potential - Use all valid and applicable data, including data collected using methods not approved under 40 CFR Part 136 (e.g. Methods 1668C and 8082A).

- EPA’s *Technical Support Document (TSD)*, Section 3.2 supports the use of all available information when evaluating reasonable potential, including available data and available narrative information.
- Effluent congener data from Method 1668C analysis should undergo 10x blank censoring (see Section 4.5.3) prior to the reasonable potential evaluation in order to sum the individual congener results. This reduces the probability of accounting for false positives in the final sum and avoids artificially high results.
- Evaluating reasonable potential for small dischargers can be done with a narrative site specific review. As with every reasonable potential determination, the process and rationale should be included in the fact sheet. Most small dischargers will not have any

monitoring data for PCBs as they are not required to conduct priority pollutant scans. When a small facility discharges to an unlisted water body, evaluate reasonable potential based on non-numeric data (e.g. significant industrial dischargers (SIUs), legacy sources, and other site specific information). If no reasonable potential is found, no further action is required. In the event of a discharge to a 303(d) listed water body with no EPA approved TMDL, again evaluate reasonable potential based on non-numeric data. If no potential is found, no further action is required. In the event of a reasonable potential determination, first implement BMPs with pollutant minimization and adaptive management requirements designed to achieve compliance with water quality standards. Monitoring must be part of this narrative effluent limit to develop a usable data set during the current permit cycle. This should be used in the next permit cycle to develop numeric limits when they are feasible. An AKART determination (see below) may be required at this time. Also, it may be necessary to investigate the applicability of a compliance schedule or variance (see Chapter 6, Section 3.3.13 or Chapter 16, Section 2, respectively).

- The following evaluation of reasonable potential applies to both large municipalities (> 1 MGD) and industrial discharges. When discharging to an unlisted waterbody, evaluate reasonable potential based on existing SIUs, data in the permit application, and all site specific information. This may be a narrative evaluation when the only facility-specific data for PCBs shows non-detects. Document the evaluation and results in the fact sheet. In the event of a discharge to a 303(d) listed surface water body with no EPA approved TMDL, again evaluate potential to exceed based on SIUs, data in the permit application, and all site specific information. When reasonable potential is found and contamination is expected, begin data collection for further characterization and/or effluent limit development. In addition, implement BMPs with pollutant minimization and adaptive management requirements designed to achieve compliance with water quality standards. Monitoring must be part of this narrative effluent limit to develop a usable data set during the current permit cycle. Increasingly sensitive analytical methods may be necessary for quantification purposes. This data must be used in the next permit cycle to develop numeric limits when they are feasible. An AKART determination (see below) may be required at this time. Also, it may be necessary to investigate the applicability of a compliance schedule or variance (see Chapter 6, Section 3.3.13 or Chapter 16, Section 2, respectively).

Requiring monitoring to complete a permit application – Use only 40 CFR Part 136 methods (e.g. Method 608.3).

- 40 CFR 122.21(e)(3) says the application shall not be considered complete unless 40 CFR Part 136 approved methods are used.
- Review the laboratory's accompanying QA/QC report supplied with the required application monitoring for accurate reporting limits and methods. Handle qualified data in accordance with Section 4.3.

Calculating numeric effluent limits - Use all valid and applicable data, including data collected using methods not approved under 40 CFR Part 136 (e.g. Methods 1668C and 8082A). Refer to Section 4.3 for discussion related to qualified data manipulation.

- Effluent limits are required when there is reasonable potential (RP). Numeric effluent limits are required where it is feasible to calculate them (based on data availability, discharge duration, and variability). If valid data collected using a more sensitive but non-Part 136 method make it feasible to calculate limits, those data should be used to calculate the numeric effluent limit.
 - Ecology has previously determined that it is infeasible to calculate a numeric effluent limit based on human health criteria for intermittent wet weather discharges (e.g., stormwater, treated CSOs). See *Permit Writer's Manual, Appendix C, 6.1 Critical Effluent Flow* for details.
- Follow procedures in PermitCalc when developing water quality-based effluent limits (WQBEL). Performance-based effluent limits are appropriate when using a compliance schedule to meet a WQBEL.

Evaluating compliance with numeric effluent limits – Use only 40 CFR Part 136 methods. For PCBs, this is Method 608.3.

- 40 CFR 122.44(i)(1) specifically requires monitoring *to assure compliance with permit limitations* according to Part 136 approved methods. If available data were collected using a congener method (e.g. 1668C) and compliance is evaluated using an Aroclor method (e.g. 608), the fact sheet should note the differences between the methods, including a discussion of both the correlation of results between methods and overlap within each method when summing individual compounds to calculate a total value.

Conducting analysis for All Known Available and Reasonable Technology (AKART) - Use methods appropriate for the facility.

- As a toxic pollutant, PCBs are subject to WAC 173-220-130 and RCW 90.48.520, which require the application of all known, available, and reasonable methods to control toxicants in the applicant's wastewater (also known as AKART). Expect AKART determinations to be different based on the size, type, and location of treatment facilities. Application of AKART must be well documented in the fact sheet.
- Methods of control for PCBs may include, but are not limited to, treatment technology, source control, best management practices, and adaptive management.
- A general discussion about AKART and how it is applied in wastewater discharge permits is provided in Section 3 of Chapter 4 in Ecology's *Water Quality Program Permit Writer's Manual*.
- For the purposes of applying AKART, Method 1668C may be required where identification of sources based on congener profile is necessary, or where expected concentrations are below analytical levels achievable by 608.3, and where treatment to lower levels is found to be reasonable. Site-specific factors, wastewater characteristics and sources must be considered when choosing the appropriate test method.

Evaluating effectiveness of best management practices - Use methods appropriate for evaluating the effectiveness of the best management practice (BMP).

- PCB analytical method selection will depend on expected concentrations in the sampled media, the BMPs required or selected, and the potential sources of PCBs on and to the site or facility. For example:
 - A PCB Aroclor Method (608.3 or 8082A) would typically be required where it is sufficiently sensitive to evaluate the effectiveness of the BMP. For example, a source tracing program aimed at finding and addressing PCB sources to stormwater at individual industrial properties based on PCB concentrations in catch basin solids, which are routinely detectable using Method 8082A.
 - Method 1668C would typically be required for source identification when the potential sources are likely to have different congener profiles, are more diffuse, or where the media sampled is unlikely to show detections using 608.3 or 8082A. Where the sources of PCBs on an individual property are not known, PCB congener data may be useful in identifying sources on and to the site. Congener data may be effective in track down sampling within a collection system, too. Blank censoring is also used to evaluate sources through effectiveness monitoring. Section 4.5.3 discusses censoring congeners that are less than 10x the laboratory blank for verifying the presence or absence of the molecule in a sample. Other data quality objectives, such as source identification, could use different censoring techniques that use different multipliers (e.g. 3x or 5x). The QAPP must specify if a different multiplier is used to censor data. Otherwise, use the 10x multiplier as the default value. Use of these different censoring strategies equate to varying levels of confidence in the analysis and should be explained both in the fact sheet and required QAPP. These data may be used to evaluate trends over time and to quantify reductions in influent, effluent and/or receiving waters.
- Use of surrogate parameters to evaluate the effectiveness of BMPs may be appropriate in lieu of PCB analysis if a surrogate parameter is available and appropriate. A correlation between the surrogate parameter and PCB concentration must be made on a site-specific basis to apply this effectiveness evaluation. For example, it might be possible to develop a correlation between TSS reduction and PCBs.
- Monitoring of media other than water can provide appropriate surrogate data using a less sensitive method. For example, evaluation of PCB concentrations in sludge/biosolids in municipal wastewater treatment can be an indicator of the effectiveness of pollution prevention and pretreatment efforts to reduce PCB concentrations in discharges to both the treatment facility and receiving water.
- If a reasonable potential is found, numeric effluent limits are required when it is feasible to calculate them. BMPs may also be required in this case, but must not be used in-lieu of numeric limits. Permits with both numeric limits and BMPs may require monitoring using two different methods for two different purposes (e.g., Method 608.3 for monitoring to assess compliance with a numeric effluent limit and Methods 1668C or 8082A for BMP effectiveness monitoring).
- Where it is infeasible to calculate numeric limits (e.g. stormwater and satellite CSO treatment plants), non-Part 136 methods may be used for evaluating BMPs, conducting adaptive management, and source identification. See Chapter 7, Section 5.1, for more information on feasibility.

Appendix C

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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.

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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: U.S. EPA, Mail Code 4203M, 1200 Pennsylvania Ave. NW, Washington, DC 20460 or by visiting <http://www.epa.gov/npdes>. Applications for EPA-issued permits must be submitted as follows:

(A) All applicants, other than POTWs, TWTDS, vessels, and pesticide applicators 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.

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

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(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, electronic mail address 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.

(iii) Notwithstanding paragraphs (c)(2)(i) or (ii) of this section, the Director may require permit applications

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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.

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

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

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

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

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

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

(ii) When there is no analytical method that has been approved under 40

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CFR part 136, required under 40 CFR chapter I, subchapter N or O, and is not otherwise required by the Director, the applicant may use any suitable method but shall provide a description of the method. When selecting a suitable method, other factors such as a method's precision, accuracy, or resolution, may be considered when assessing the performance of the method.

(f) *Information requirements.* All applicants for NPDES permits, other than POTWs and other TWTDS, vessels, and pesticide applicators, must provide the information in paragraphs (f)(1) through (10) of this section to the Director, using the application form provided by the Director. Additional information required of applicants is set forth in paragraphs (g) through (k) and (q) through (r) 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 and up to four NAICS codes that best reflect the principal products or services provided by the facility.

(4) The operator's name, address, telephone number, electronic mail address, 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.

(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.

(9) An indication of whether the facility uses cooling water and the source of the cooling water.

(10) An indication of whether the facility is requesting any of the variances at 40 CFR 122.21(m), if known at the time of application.

(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 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 (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).

(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.

(ix) Where quantitative data are required in paragraphs (g)(7)(i) through (viii) of this section, existing data may be used, if available, in lieu of sampling done solely for the purpose of the application, provided that: All data requirements are met; sampling was performed, collected, and analyzed no more than four and one-half years prior to submission; all data are representative of the discharge; and all available representative data are considered in the values reported.

(8) *Small business exemption.* An application which qualifies as a small business under one of the following criteria is exempt from the requirements in

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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 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.

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(iii) Develop recommendations for areas that would be considered “potentially impacted public access areas” as referenced in § 122.38(a)(1), (2), and (3).

(2) Seek input from other potentially affected public entities and Indian Tribes whose waters may be impacted by a CSO discharge.

(3) Consider the recommendations of the public health department and other potentially affected entities in developing protocols in its public notification plan for providing notification of CSO discharges to the public health department and potentially affected public entities and Indian Tribes.

(e) *Extending compliance to avoid undue economic hardship.* The Director may extend the compliance dates in paragraphs (a), (b), and (c) of this section for individual communities if the Director determines the community needs additional time to comply in order to avoid undue economic hardship. Where the Director extends the compliance date of any of these requirements for a community, the Director shall notify the Regional Administrator of the extension and the reason for the extension. The Director shall post on its website a notice that includes the name of the community and the new compliance date(s). The notice shall remain on the Director’s website until the new compliance date.

[83 FR 730, Jan. 8, 2018]

Subpart C—Permit Conditions

§ 122.41 Conditions applicable to all permits (applicable to State programs, see § 123.25).

The following conditions apply to all NPDES permits. Additional conditions applicable to NPDES permits are in § 122.42. All conditions applicable to NPDES permits shall be incorporated into the permits either expressly or by reference. If incorporated by reference, a specific citation to these regulations (or the corresponding approved State regulations) must be given in the permit.

(a) *Duty to comply.* The permittee must comply with all conditions of this permit. Any permit noncompliance constitutes a violation of the Clean Water Act and is grounds for enforcement action; for permit termination,

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revocation and reissuance, or modification; or denial of a permit renewal application.

(1) The permittee shall comply with effluent standards or prohibitions established under section 307(a) of the Clean Water Act for toxic pollutants and with standards for sewage sludge use or disposal established under section 405(d) of the CWA within the time provided in the regulations that establish these standards or prohibitions or standards for sewage sludge use or disposal, even if the permit has not yet been modified to incorporate the requirement.

(2) The Clean Water Act provides that any person who violates section 301, 302, 306, 307, 308, 318 or 405 of the Act, or any permit condition or limitation implementing any such sections in a permit issued under section 402, or any requirement imposed in a pretreatment program approved under sections 402(a)(3) or 402(b)(8) of the Act, is subject to a civil penalty not to exceed \$25,000 per day for each violation. The Clean Water Act provides that any person who *negligently* violates sections 301, 302, 306, 307, 308, 318, or 405 of the Act, or any condition or limitation implementing any of such sections in a permit issued under section 402 of the Act, or any requirement imposed in a pretreatment program approved under section 402(a)(3) or 402(b)(8) of the Act, is subject to criminal penalties of \$2,500 to \$25,000 per day of violation, or imprisonment of not more than 1 year, or both. In the case of a second or subsequent conviction for a negligent violation, a person shall be subject to criminal penalties of not more than \$50,000 per day of violation, or by imprisonment of not more than 2 years, or both. Any person who *knowingly* violates such sections, or such conditions or limitations is subject to criminal penalties of \$5,000 to \$50,000 per day of violation, or imprisonment for not more than 3 years, or both. In the case of a second or subsequent conviction for a knowing violation, a person shall be subject to criminal penalties of not more than \$100,000 per day of violation, or imprisonment of not more than 6 years, or both. Any person who knowingly violates section 301, 302, 303, 306, 307, 308, 318 or 405 of the Act, or any

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permit condition or limitation implementing any of such sections in a permit issued under section 402 of the Act, and who knows at that time that he thereby places another person in imminent danger of death or serious bodily injury, shall, upon conviction, be subject to a fine of not more than \$250,000 or imprisonment of not more than 15 years, or both. In the case of a second or subsequent conviction for a knowing endangerment violation, a person shall be subject to a fine of not more than \$500,000 or by imprisonment of not more than 30 years, or both. An organization, as defined in section 309(c)(3)(B)(iii) of the CWA, shall, upon conviction of violating the imminent danger provision, be subject to a fine of not more than \$1,000,000 and can be fined up to \$2,000,000 for second or subsequent convictions.

(3) Any person may be assessed an administrative penalty by the Administrator for violating section 301, 302, 306, 307, 308, 318 or 405 of this Act, or any permit condition or limitation implementing any of such sections in a permit issued under section 402 of this Act. Administrative penalties for Class I violations are not to exceed \$10,000 per violation, with the maximum amount of any Class I penalty assessed not to exceed \$25,000. Penalties for Class II violations are not to exceed \$10,000 per day for each day during which the violation continues, with the maximum amount of any Class II penalty not to exceed \$125,000.

(b) *Duty to reapply.* If the permittee wishes to continue an activity regulated by this permit after the expiration date of this permit, the permittee must apply for and obtain a new permit.

(c) *Need to halt or reduce activity not a defense.* It shall not be a defense for a permittee in an enforcement action that it would have been necessary to halt or reduce the permitted activity in order to maintain compliance with the conditions of this permit.

(d) *Duty to mitigate.* The permittee shall take all reasonable steps to minimize or prevent any discharge or sludge use or disposal in violation of this permit which has a reasonable likelihood of adversely affecting human health or the environment.

(e) *Proper operation and maintenance.* The permittee shall at all times properly operate and maintain all facilities and systems of treatment and control (and related appurtenances) which are installed or used by the permittee to achieve compliance with the conditions of this permit. Proper operation and maintenance also includes adequate laboratory controls and appropriate quality assurance procedures. This provision requires the operation of back-up or auxiliary facilities or similar systems which are installed by a permittee only when the operation is necessary to achieve compliance with the conditions of the permit.

(f) *Permit actions.* This permit may be modified, revoked and reissued, or terminated for cause. The filing of a request by the permittee for a permit modification, revocation and reissuance, or termination, or a notification of planned changes or anticipated noncompliance does not stay any permit condition.

(g) *Property rights.* This permit does not convey any property rights of any sort, or any exclusive privilege.

(h) *Duty to provide information.* The permittee shall furnish to the Director, within a reasonable time, any information which the Director may request to determine whether cause exists for modifying, revoking and reissuing, or terminating this permit or to determine compliance with this permit. The permittee shall also furnish to the Director upon request, copies of records required to be kept by this permit.

(i) *Inspection and entry.* The permittee shall allow the Director, or an authorized representative (including an authorized contractor acting as a representative of the Administrator), upon presentation of credentials and other documents as may be required by law, to:

(1) Enter upon the permittee's premises where a regulated facility or activity is located or conducted, or where records must be kept under the conditions of this permit;

(2) Have access to and copy, at reasonable times, any records that must be kept under the conditions of this permit;

(3) Inspect at reasonable times any facilities, equipment (including monitoring and control equipment), practices, or operations regulated or required under this permit; and

(4) Sample or monitor at reasonable times, for the purposes of assuring permit compliance or as otherwise authorized by the Clean Water Act, any substances or parameters at any location.

(j) *Monitoring and records.* (1) Samples and measurements taken for the purpose of monitoring shall be representative of the monitored activity.

(2) Except for records of monitoring information required by this permit related to the permittee's sewage sludge use and disposal activities, which shall be retained for a period of at least five years (or longer as required by 40 CFR part 503), the permittee shall retain records of all monitoring information, including all calibration and maintenance records and all original strip chart recordings for continuous monitoring instrumentation, copies of all reports required by this permit, and records of all data used to complete the application for this permit, for a period of at least 3 years from the date of the sample, measurement, report or application. This period may be extended by request of the Director at any time.

(3) Records of monitoring information shall include:

(i) The date, exact place, and time of sampling or measurements;

(ii) The individual(s) who performed the sampling or measurements;

(iii) The date(s) analyses were performed;

(iv) The individual(s) who performed the analyses;

(v) The analytical techniques or methods used; and

(vi) The results of such analyses.

(4) Monitoring must be conducted according to test procedures approved under 40 CFR Part 136 unless another method is required under 40 CFR subchapters N or O.

(5) The Clean Water Act provides that any person who falsifies, tampers with, or knowingly renders inaccurate any monitoring device or method required to be maintained under this permit shall, upon conviction, be punished by a fine of not more than \$10,000, or by imprisonment for not more than 2

years, or both. If a conviction of a person is for a violation committed after a first conviction of such person under this paragraph, punishment is a fine of not more than \$20,000 per day of violation, or by imprisonment of not more than 4 years, or both.

(k) *Signatory requirement.* (1) All applications, reports, or information submitted to the Director shall be signed and certified. (See §122.22)

(2) The CWA provides that any person who knowingly makes any false statement, representation, or certification in any record or other document submitted or required to be maintained under this permit, including monitoring reports or reports of compliance or non-compliance shall, upon conviction, be punished by a fine of not more than \$10,000 per violation, or by imprisonment for not more than 6 months per violation, or by both.

(l) *Reporting requirements—(1) Planned changes.* The permittee shall give notice to the Director as soon as possible of any planned physical alterations or additions to the permitted facility. Notice is required only when:

(i) The alteration or addition to a permitted facility may meet one of the criteria for determining whether a facility is a new source in §122.29(b); or

(ii) The alteration or addition could significantly change the nature or increase the quantity of pollutants discharged. This notification applies to pollutants which are subject neither to effluent limitations in the permit, nor to notification requirements under §122.42(a)(1).

(iii) The alteration or addition results in a significant change in the permittee's sludge use or disposal practices, and such alteration, addition, or change may justify the application of permit conditions that are different from or absent in the existing permit, including notification of additional use or disposal sites not reported during the permit application process or not reported pursuant to an approved land application plan;

(2) *Anticipated noncompliance.* The permittee shall give advance notice to the Director of any planned changes in the permitted facility or activity which may result in noncompliance with permit requirements.

SUBCHAPTER D—WATER PROGRAMS (CONTINUED)

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

Sec.

136.1 Applicability.

136.2 Definitions.

136.3 Identification of test procedures.

136.4 Application for and approval of alternate test procedures for nationwide use.

136.5 Approval of alternate test procedures for limited use.

136.6 Method modifications and analytical requirements.

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APPENDIX A TO PART 136—METHODS FOR ORGANIC CHEMICAL ANALYSIS OF MUNICIPAL AND INDUSTRIAL WASTEWATER

APPENDIX B TO PART 136—DEFINITION AND PROCEDURE FOR THE DETERMINATION OF THE METHOD DETECTION LIMIT—REVISION 1.11

APPENDIX C TO PART 136—DETERMINATION OF METALS AND TRACE ELEMENTS IN WATER AND WASTES BY INDUCTIVELY COUPLED PLASMA-ATOMIC EMISSION SPECTROMETRY METHOD 200.7

APPENDIX D TO PART 136—PRECISION AND RECOVERY STATEMENTS FOR METHODS FOR MEASURING METALS

AUTHORITY: Secs. 301, 304(h), 307 and 501(a), Pub. L. 95-217, 91 Stat. 1566, *et seq.* (33 U.S.C. 1251, *et seq.*) (the Federal Water Pollution Control Act Amendments of 1972 as amended by the Clean Water Act of 1977).

§ 136.1 Applicability.

(a) The procedures prescribed herein shall, except as noted in §§ 136.4, 136.5, and 136.6, be used to perform the measurements indicated whenever the waste constituent specified is required to be measured for:

(1) An application submitted to the Director and/or reports required to be submitted under NPDES permits or other requests for quantitative or qualitative effluent data under parts 122 through 125 of this chapter; and

(2) Reports required to be submitted by dischargers under the NPDES established by parts 124 and 125 of this chapter; and

(3) Certifications issued by States pursuant to section 401 of the Clean Water Act (CWA), as amended.

(b) The procedure prescribed herein and in part 503 of title 40 shall be used

to perform the measurements required for an application submitted to the Administrator or to a State for a sewage sludge permit under section 405(f) of the Clean Water Act and for record-keeping and reporting requirements under part 503 of title 40.

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

[72 FR 14224, Mar. 26, 2007, as amended at 77 FR 29771, May 18, 2012; 79 FR 49013, Aug. 19, 2014; 82 FR 40846, Aug. 28, 2017]

§ 136.2 Definitions.

As used in this part, the term:

(a) *Act* means the Clean Water Act of 1977, Pub. L. 95-217, 91 Stat. 1566, *et seq.* (33 U.S.C. 1251 *et seq.*) (The Federal Water Pollution Control Act Amendments of 1972 as amended by the Clean Water Act of 1977).

(b) *Administrator* means the Administrator of the U.S. Environmental Protection Agency.

(c) *Regional Administrator* means one of the EPA Regional Administrators.

(d) *Director* means the director as defined in 40 CFR 122.2.

(e) *National Pollutant Discharge Elimination System (NPDES)* means the national system for the issuance of permits under section 402 of the Act and includes any State or interstate program which has been approved by the Administrator, in whole or in part, pursuant to section 402 of the Act.

(f) *Detection limit* means the minimum concentration of an analyte (substance) that can be measured and reported with a 99% confidence that the analyte concentration is distinguishable from the method blank results as determined by the procedure set forth at appendix B of this part.

[38 FR 28758, Oct. 16, 1973, as amended at 49 FR 43250, Oct. 26, 1984; 82 FR 40846, Aug. 28, 2017]

§ 136.3

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§ 136.3 Identification of test procedures.

(a) Parameters or pollutants, for which methods are approved, are listed together with test procedure descriptions and references in Tables IA, IB, IC, ID, IE, IF, IG, and IH of this section. The methods listed in Tables IA, IB, IC, ID, IE, IF, IG, and IH are incorporated by reference, see paragraph (b) of this section, with the exception of EPA Methods 200.7, 601–613, 624.1, 625.1, 1613, 1624, and 1625. The full texts of Methods 601–613, 624.1, 625.1, 1613, 1624, and 1625 are printed in appendix A of this part, and the full text of Method 200.7 is printed in appendix C of this part. The full text for determining the method detection limit when using the test procedures is given in appendix B of this part. In the event of a conflict between the reporting requirements of 40 CFR parts 122 and 125 and any reporting requirements associated with

the methods listed in these tables, the provisions of 40 CFR parts 122 and 125 are controlling and will determine a permittee's reporting requirements. The full texts of the referenced test procedures are incorporated by reference into Tables IA, IB, IC, ID, IE, IF, IG, and IH. The year after the method number indicates the latest editorial change of the method. The discharge parameter values for which reports are required must be determined by one of the standard analytical test procedures incorporated by reference and described in Tables IA, IB, IC, ID, IE, IF, IG, and IH or by any alternate test procedure which has been approved by the Administrator under the provisions of paragraph (d) of this section and §§ 136.4 and 136.5. Under certain circumstances (paragraph (c) of this section, in § 136.5(a) through (d) or 40 CFR 401.13) other additional or alternate test procedures may be used.

TABLE IC—LIST OF APPROVED TEST PROCEDURES FOR NON-PESTICIDE ORGANIC COMPOUNDS—Continued

Parameter ¹	Method	EPA ^{2,7}	Standard methods	ASTM	Other
114. Nonylphenol	GC/MS	D7065-11.	
115. Bisphenol A (BPA)	GC/MS	D7065-11.	
116. <i>p</i> -tert-Octylphenol (OP)	GC/MS	D7065-11.	
117. Nonylphenol Monooxylate (NP1EO).	GC/MS	D7065-11.	
118. Nonylphenol Diethoxylate (NP2EO).	GC/MS	D7065-11.	
119. Adsorbable Organic Halides (AOX).	Adsorption and Coulometric Titra- tion.	1650 ¹¹		
120. Chlorinated Phenolics	In Situ Acetylation and GC/MS.	1653 ¹¹ .			

Table IC notes:

- ¹ All parameters are expressed in micrograms per liter (µg/L) except for Method 1613B, in which the parameters are expressed in picograms per liter (pg/L).
- ² The full text of Methods 601-613, 1613B, 1624B, and 1625B are provided at appendix A, Test Procedures for Analysis of Organic Pollutants. The standardized test procedure to be used to determine the method detection limit (MDL) for these test procedures is given at appendix B of this part, Definition and Procedure for the Determination of the Method Detection Limit. These methods are available at: <https://www.epa.gov/cwa-methods> as individual PDF files.
- ³ Methods for Benzidine: Chlorinated Organic Compounds, Pentachlorophenol and Pesticides in Water and Wastewater. September 1978. U.S. EPA.
- ⁴ Method 624.1 may be used for quantitative determination of acrolein and acrylonitrile, provided that the laboratory has documentation to substantiate the ability to detect and quantify these analytes at levels necessary to comply with any associated regulations. In addition, the use of sample introduction techniques other than simple purge-and-trap may be required. QC acceptance criteria from Method 603 should be used when analyzing samples for acrolein and acrylonitrile in the absence of such criteria in Method 624.1.
- ⁵ Method 625.1 may be extended to include benzidine, hexachlorocyclopentadiene, N-nitrosodimethylamine, N-nitrosodi-n-propylamine, and N-nitrosodiphenylamine. However, when they are known to be present, Methods 605, 607, and 612, or Method 1625B, are preferred methods for these compounds.
- ^{5a} Method 625.1 screening only.
- ⁶ Selected Analytical Methods Approved and Cited by the United States Environmental Protection Agency, Supplement to the 15th Edition of *Standard Methods for the Examination of Water and Wastewater*. 1981. American Public Health Association (APHA).
- ⁷ Each analyst must make an initial, one-time demonstration of their ability to generate acceptable precision and accuracy with Methods 601-603, 1624B, and 1625B in accordance with procedures each in Section 8.2 of each of these Methods. Additionally, each laboratory, on an on-going basis must spike and analyze 10% (5% for Methods 624.1 and 625.1 and 100% for methods 1624B and 1625B) of all samples to monitor and evaluate laboratory data quality in accordance with Sections 8.3 and 8.4 of these methods. When the recovery of any parameter falls outside the quality control (QC) acceptance criteria in the pertinent method, analytical results for that parameter in the unspiked sample are suspect. The results should be reported but cannot be used to demonstrate regulatory compliance. If the method does not contain QC acceptance criteria, control limits of ± three standard deviations around the mean of a minimum of five replicate measurements must be used. These quality control requirements also apply to the Standard Methods, ASTM Methods, and other methods cited.
- ⁸ Organochlorine Pesticides and PCBs in Wastewater Using Empore™ Disk. Revised October 28, 1994. 3M Corporation.
- ⁹ Method O-3116-87 is in Open File Report 93-125, Methods of Analysis by U.S. Geological Survey National Water Quality Laboratory—Determination of Inorganic and Organic Constituents in Water and Fluvial Sediments. 1993. USGS.
- ¹⁰ Analysts may use Fluid Management Systems, Inc. Power-Prep system in place of manual cleanup provided the analyst meets the requirements of Method 1613B (as specified in Section 9 of the method) and permitting authorities. Method 1613, Revision B, Tetra- through Octa-Chlorinated Dioxins and Furans by Isotope Dilution HRGC/HRMS. Revision B, 1994. U.S. EPA. The full text of this method is provided in appendix A to this part and at [https://www.epa.gov/cwa-methods-organic-compounds](https://www.epa.gov/cwa-methods/approved-cwa-methods-organic-compounds).

§ 136.4

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[38 FR 28758, Oct. 16, 1973]

EDITORIAL NOTE: For FEDERAL REGISTER citations affecting § 136.3, see the List of CFR Sections Affected, which appears in the Finding Aids section of the printed volume and at www.govinfo.gov.

§ 136.4 Application for and approval of alternate test procedures for nationwide use.

(a) A written application for review of an alternate test procedure (alternate method) for nationwide use may be made by letter via email or by hard copy in triplicate to the National Alternate Test Procedure (ATP) Program Coordinator (National Coordinator), Office of Science and Technology (4303T), Office of Water, U.S. Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460. Any application for an ATP under this paragraph (a) shall:

(1) Provide the name and address of the responsible person or firm making the application.

(2) Identify the pollutant(s) or parameter(s) for which nationwide approval of an alternate test procedure is being requested.

(3) Provide a detailed description of the proposed alternate test procedure, together with references to published or other studies confirming the general applicability of the alternate test procedure for the analysis of the pollutant(s) or parameter(s) in wastewater discharges from representative and specified industrial or other categories.

(4) Provide comparability data for the performance of the proposed alternative test procedure compared to the performance of the reference method.

(b) The National Coordinator may request additional information and analyses from the applicant in order to evaluate whether the alternate test procedure satisfies the applicable requirements of this part.

(c) *Approval for nationwide use.* (1) After a review of the application and any additional analyses requested from the applicant, the National Coordinator will notify the applicant, in writing, of whether the National Coordinator will recommend approval or disapproval of the alternate test procedure for nationwide use in CWA programs. If the application is not recommended for approval, the National

Coordinator may specify what additional information might lead to a reconsideration of the application and notify the Regional Alternate Test Procedure Coordinators of the disapproval recommendation. Based on the National Coordinator's recommended disapproval of a proposed alternate test procedure and an assessment of any current approvals for limited uses for the unapproved method, the Regional ATP Coordinator may decide to withdraw approval of the method for limited use in the Region.

(2) Where the National Coordinator has recommended approval of an applicant's request for nationwide use of an alternate test procedure, the National Coordinator will notify the applicant. The National Coordinator will also notify the Regional ATP Coordinators that they may consider approval of this alternate test procedure for limited use in their Regions based on the information and data provided in the application until the alternate test procedure is approved by publication in a final rule in the FEDERAL REGISTER.

(3) EPA will propose to amend this part to include the alternate test procedure in § 136.3. EPA shall make available for review all the factual bases for its proposal, including the method, any performance data submitted by the applicant and any available EPA analysis of those data.

(4) Following public comment, EPA shall publish in the FEDERAL REGISTER a final decision on whether to amend this part to include the alternate test procedure as an approved analytical method for nationwide use.

(5) Whenever the National Coordinator has recommended approval of an applicant's ATP request for nationwide use, any person may request an approval of the method for limited use under § 136.5 from the EPA Region.

[77 FR 29809, May 18, 2012, as amended at 82 FR 40874, Aug. 28, 2017]

Environmental Protection Agency

§ 136.6

§ 136.5 Approval of alternate test procedures for limited use.

(a) Any person may request the Regional ATP Coordinator to approve the use of an alternate test procedure in the Region.

(b) When the request for the use of an alternate test procedure concerns use in a State with an NPDES permit program approved pursuant to section 402 of the Act, the requestor shall first submit an application for limited use to the Director of the State agency having responsibility for issuance of NPDES permits within such State (*i.e.*, permitting authority). The Director will forward the application to the Regional ATP Coordinator with a recommendation for or against approval.

(c) Any application for approval of an alternate test procedure for limited use may be made by letter, email or by hard copy. The application shall include the following:

(1) Provide the name and address of the applicant and the applicable ID number of the existing or pending permit(s) and issuing agency for which use of the alternate test procedure is requested, and the discharge serial number.

(2) Identify the pollutant or parameter for which approval of an alternate test procedure is being requested.

(3) Provide justification for using testing procedures other than those specified in Tables IA through IH of § 136.3, or in the NPDES permit.

(4) Provide a detailed description of the proposed alternate test procedure, together with references to published studies of the applicability of the alternate test procedure to the effluents in question.

(5) Provide comparability data for the performance of the proposed alternate test procedure compared to the performance of the reference method.

(d) *Approval for limited use.* (1) The Regional ATP Coordinator will review the application and notify the applicant and the appropriate State agency of approval or rejection of the use of the alternate test procedure. The approval may be restricted to use only with respect to a specific discharge or facility (and its laboratory) or, at the discretion of the Regional ATP Coordinator, to all dischargers or facilities

(and their associated laboratories) specified in the approval for the Region. If the application is not approved, the Regional ATP Coordinator shall specify what additional information might lead to a reconsideration of the application.

(2) The Regional ATP Coordinator will forward a copy of every approval and rejection notification to the National Alternate Test Procedure Coordinator.

[77 FR 29809, May 18, 2012, as amended at 82 FR 40875, Aug. 28, 2017]

§ 136.6 Method modifications and analytical requirements.

(a) *Definitions of terms used in this section*—(1) *Analyst* means the person or laboratory using a test procedure (analytical method) in this part.

(2) *Chemistry of the method* means the reagents and reactions used in a test procedure that allow determination of the analyte(s) of interest in an environmental sample.

(3) *Determinative technique* means the way in which an analyte is identified and quantified (e.g., colorimetry, mass spectrometry).

(4) *Equivalent performance* means that the modified method produces results that meet or exceed the QC acceptance criteria of the approved method.

(5) *Method-defined analyte* means an analyte defined solely by the method used to determine the analyte. Such an analyte may be a physical parameter, a parameter that is not a specific chemical, or a parameter that may be comprised of a number of substances. Examples of such analytes include temperature, oil and grease, total suspended solids, total phenolics, turbidity, chemical oxygen demand, and biochemical oxygen demand.

(6) *QC* means “quality control.”

(b) *Method modifications.* (1) If the underlying chemistry and determinative technique in a modified method are essentially the same as an approved Part 136 method, then the modified method is an equivalent and acceptable alternative to the approved method provided the requirements of this section are met. However, those who develop or use a modification to an approved (Part 136) method must document that

WAC 173-201A-260 Natural conditions and other water quality criteria and applications. (1) Natural and irreversible human conditions.

(a) It is recognized that portions of many water bodies cannot meet the assigned criteria due to the natural conditions of the water body. When a water body does not meet its assigned criteria due to natural climatic or landscape attributes, the natural conditions constitute the water quality criteria.

(b) When a water body does not meet its assigned criteria due to human structural changes that cannot be effectively remedied (as determined consistent with the federal regulations at 40 C.F.R. 131.10), then alternative estimates of the attainable water quality conditions, plus any further allowances for human effects specified in this chapter for when natural conditions exceed the criteria, may be used to establish an alternative criteria for the water body (see WAC 173-201A-430 and 173-201A-440).

(2) **Toxics and aesthetics criteria.** The following narrative criteria apply to all existing and designated uses for fresh and marine water:

(a) Toxic, radioactive, or deleterious material concentrations must be below those which have the potential, either singularly or cumulatively, to adversely affect characteristic water uses, cause acute or chronic conditions to the most sensitive biota dependent upon those waters, or adversely affect public health (see WAC 173-201A-240, toxic substances, and 173-201A-250, radioactive substances).

(b) Aesthetic values must not be impaired by the presence of materials or their effects, excluding those of natural origin, which offend the senses of sight, smell, touch, or taste (see WAC 173-201A-230 for guidance on establishing lake nutrient standards to protect aesthetics).

(3) **Procedures for applying water quality criteria.** In applying the appropriate water quality criteria for a water body, the department will use the following procedure:

(a) The department will establish water quality requirements for water bodies, in addition to those specifically listed in this chapter, on a case-specific basis where determined necessary to provide full support for designated and existing uses.

(b) Upstream actions must be conducted in manners that meet downstream water body criteria. Except where and to the extent described otherwise in this chapter, the criteria associated with the most upstream uses designated for a water body are to be applied to headwaters to protect nonfish aquatic species and the designated downstream uses.

(c) Where multiple criteria for the same water quality parameter are assigned to a water body to protect different uses, the most stringent criterion for each parameter is to be applied.

(d) At the boundary between water bodies protected for different uses, the more stringent criteria apply.

(e) In brackish waters of estuaries, where different criteria for the same use occurs for fresh and marine waters, the decision to use the fresh water or the marine water criteria must be selected and applied on the basis of vertically averaged daily maximum salinity, referred to below as "salinity."

(i) The fresh water criteria must be applied at any point where ninety-five percent of the salinity values are less than or equal to one part per thousand, except that the fresh water criteria for bacteria applies when the salinity is less than ten parts per thousand; and

(ii) The marine water criteria must apply at all other locations where the salinity values are greater than one part per thousand, except that the marine criteria for bacteria applies when the salinity is ten parts per thousand or greater.

(f) Numeric criteria established in this chapter are not intended for application to human created waters managed primarily for the removal or containment of pollution. This special provision also includes private farm ponds created from upland sites that did not incorporate natural water bodies.

(i) Waters covered under this provision must be managed so that:

(A) They do not create unreasonable risks to human health or uses of the water; and

(B) Discharges from these systems meet down gradient surface and ground water quality standards.

(ii) This provision does not apply to waterways designed and managed primarily to convey or transport water from one location to another, rather than to remove pollution en route.

(g) When applying the numeric criteria established in this chapter, the department will give consideration to the precision and accuracy of the sampling and analytical methods used, as well as the existing conditions at the time.

(h) The analytical testing methods for these numeric criteria must be in accordance with the "*Guidelines Establishing Test Procedures for the Analysis of Pollutants*" (40 C.F.R. Part 136) or superceding methods published. The department may also approve other methods following consultation with adjacent states and with the approval of the USEPA.

(i) The primary means for protecting water quality in wetlands is through implementing the antidegradation procedures described in Part III of this chapter.

(i) In addition to designated uses, wetlands may have existing beneficial uses that are to be protected that include ground water exchange, shoreline stabilization, and stormwater attenuation.

(ii) Water quality in wetlands is maintained and protected by maintaining the hydrologic conditions, hydrophytic vegetation, and substrate characteristics necessary to support existing and designated uses.

(iii) Wetlands must be delineated using the *Washington State Wetlands Identification and Delineation Manual*, in accordance with WAC 173-22-035.

[Statutory Authority: RCW 90.48.035. WSR 11-09-090 (Order 10-10), § 173-201A-260, filed 4/20/11, effective 5/21/11. Statutory Authority: Chapters 90.48 and 90.54 RCW. WSR 03-14-129 (Order 02-14), § 173-201A-260, filed 7/1/03, effective 8/1/03.]

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