

SECTION 16

NEW SOURCE PERFORMANCE STANDARDS (NSPS)

16.1 Introduction

The basis for new source performance standards under Section 306 of the CWA is the best available demonstrated technology. Industry has the opportunity to design and install the best and most efficient process operations and wastewater treatment systems at new pharmaceutical manufacturing facilities. Accordingly, Congress directed EPA to consider the best demonstrated alternative processes, process changes, in-plant control measures, and end-of-pipe wastewater treatment technologies that reduce pollution to the maximum extent feasible. In response to that directive, and as with the development of options for the BAT effluent limitations guidelines, EPA considered effluent reductions attainable by the most advanced treatment technologies at pharmaceutical manufacturing facilities.

NSPS establish quantitative limits on the direct discharge of conventional, priority, and nonconventional pollutants to waters of the United States. These standards are based upon the performance of specific advanced technologies, but do not specify which technologies must be used to achieve compliance. NSPS are applied to individual facilities through NPDES permits issued by EPA or authorized states under Section 402 of the CWA. Each facility then chooses its own approach to complying with its permit limitations.

NSPS apply to all new sources in the pharmaceutical manufacturing industry. The NPDES permit regulations define the term "new source" at 40 CFR 122.2 and 122.29. According to these regulations, to be "new", a source must:

- Be constructed at a site at which no other source is located;
- Totally replace the process or production equipment that causes the discharge of pollutants at an existing source; or

- Be a process substantially independent of an existing source at the same site, considering the extent of integration with the existing source and the extent to which the new source is engaged in the same general type of activity as the existing source.

The Agency has selected end-of-pipe advanced biological treatment with nitrification of ammonia as the technology basis for the NSPS for Subcategories A and C. The performance level of the advanced biological treatment system component of NSPS for Subcategories A and C is equivalent to the selected BPT, for COD, and BAT, for priority, nonconventional organic pollutants and ammonia. Standards for conventional pollutants (BOD₅, TSS and pH) are being established for new sources consistent with that same performance level.

The Agency has selected end-of-pipe advanced biological treatment as the technology basis for the NSPS for Subcategories B and D. The performance level of the advanced biological treatment system component of NSPS for Subcategories B and D is equivalent to the selected BPT for COD. Standards for conventional pollutants (BOD₅, TSS and pH) are being established for new sources consistent with that same performance level. The rationale behind these selections is discussed in Section 11.

The following information is presented in this section:

- Section 16.2 reviews the subcategories and the pollutants to be regulated by NSPS and presents the NSPS; and
- Section 16.3 discusses NSPS implementation with regard to point of application, permit limitations, and monitoring and compliance issues.

16.2 Summary of the NSPS

16.2.1 Regulated Subcategories

The NSPS, as discussed in Section 7.3 are for Subcategories A, B, C, and D. As discussed in Section 4.3, Subcategories A, B, and C include wastewater discharges resulting from the

manufacture of pharmaceuticals by fermentation, biological or natural extraction processes, and chemical synthesis processes, respectively. Subcategory D includes wastewater discharges resulting from mixing, compounding, and formulating of pharmaceutical products.

16.2.2 Regulated Pollutants

The NSPS establish effluent limitations for the conventional, priority, and nonconventional pollutants listed in Table 16-1 for direct dischargers in Subcategories A and C. In addition, the NSPS establish effluent limitations for the conventional, and nonconventional pollutants listed in Table 16-2 for direct dischargers in Subcategories B and D.

The NSPS in this rulemaking clarifies existing in-plant cyanide limitations for Subcategory A and C facilities. Compliance monitoring for cyanide should occur immediately after cyanide destruction, before commingling cyanide-bearing waste streams with non-cyanide-bearing waste streams, unless a facility can demonstrate that cyanide is detectable at end-of-pipe. The 1983 cyanide limitations for Subcategory B and D direct dischargers are being withdrawn; these subcategories do not use or generate cyanide.

16.2.3 NSPS

The NSPS for each subcategory are based on a combination of long-term mean effluent values and variability factors that account for day-to-day variation in measured treated effluent concentrations. Long-term means, discussed in Section 8, are target values that a facility should achieve on a long-term, average basis. The variability factors, discussed in the Statistical Support Document(1), which is located in the Administrative Record for this rulemaking, represent the ratio of an elevated value, expected to occur only rarely, to the long-term mean. The purpose of the variability factor is to allow for variations in measured effluent concentrations that comprise the long-term mean. A facility that designs and operates its treatment system to achieve a long-term mean on a consistent basis should be able to comply with the daily and monthly limitations in the course of normal operations.

EPA is promulgating NSPS equal to the final BAT effluent limitations for 30 organic pollutants, cyanide and ammonia for Subcategory A and C facilities. NSPS for Subcategory A, B, C, and D facilities are also being revised for BOD₅, COD and TSS, at a level equal to the discharge characteristics of the best performing BPT plants.

Table 16-3 presents the maximum daily and monthly average NSPS for Subcategory A, and C operations. Table 16-4 presents the maximum daily and monthly average NSPS for Subcategory B and D operations.

The NSPS for acetonitrile, benzene, diethylamine, dimethyl sulfoxide, ethanol, n-heptane, methanol, methyl cellosolve, and triethylamine are based on the analytical method minimum level. The minimum level for a pollutant is the level at which an analytical system gives recognizable signals and an acceptable calibration point. For pollutants with a long-term mean below the minimum level, typically in cases where treatment performance was established through data transfer, the final long-term mean was set at a value no lower than the minimum level for the pollutant. The final effluent limitations are determined by applying 1-day and 4-day variability factors to the final long-term means.

The pH effluent limit, established in the 1976 Final Rule (41 FR 50676) to be the range of 6.0 to 9.0 standard units for all subcategories, is not being revised. The NSPS cyanide effluent limit, established in the 1983 Final Rule to be a daily maximum of 33.5 mg/L and a maximum monthly average of 9.4 mg/L for all subcategories, is not being revised for Subcategories A and C. The cyanide effluent limit is being withdrawn for Subcategories B and D, because EPA has determined that cyanide is neither used nor generated by facilities with these subcategory operations.

16.3 Implementation of NSPS

16.3.1 Establishing List of Pollutants for Compliance Monitoring

Permitting authorities should establish permit limitations and compliance monitoring requirements for each pollutant listed in Table 16-1 for Subcategory A and C facilities, or Table 16-2 for Subcategory B and D facilities, generated or used at a pharmaceutical manufacturing facility. Limitations and routine compliance monitoring should not be required for regulated pollutants not generated or used at a facility. A determination that regulated pollutants are not generated or used should be based on a review of all raw materials and chemical processes used, considering resulting products and by-products. The determination that a regulated pollutant is not generated or used should be confirmed by annual chemical analyses of wastewater from each monitoring location. Such confirmation would be provided by an analytical measurement of a non-detect value.

Facilities discharging more than one regulated organic pollutant may monitor for a single surrogate pollutant to demonstrate an appropriate degree of control for a specified group of pollutants. For the purpose of identifying surrogates, pollutants are grouped according to treatability classes; Table 16-5 presents the treatability classes identified for advanced biological treatment, which is the BAT technology basis for organic pollutant limitations. For treatability classes with more than one possible surrogate pollutant, the analyte with the highest concentration should be chosen as the surrogate pollutant. Plants may monitor for a surrogate pollutant(s) only if they demonstrate that all other pollutants receive the same degree of treatment.

An individual plant may choose to demonstrate by selecting a monitoring pollutant for a given treatability class and maintaining documentation, including flow information and sampling results, that all pollutants in that treatability class receive equivalent treatment. The documentation is then submitted to the permit authority for approval.

16.3.2 Point of Application

The NSPS for pollutants listed in Tables 16-3 and Table 16-4 are end-of-pipe standards and are applicable to the final effluent at the point of discharge to waters of the United States, prior to non-process dilution waters. Compliance monitoring for cyanide should occur in-plant, unless a facility can show a measurable amount of cyanide at end-of-pipe, instead of a non-detect in accordance with 40 CFR 403.6 (e)(2) and 403.6 (e)(4).

16.3.3 Permit Limitations

End-of-pipe permit limitations based on the NSPS limitations for ammonia, conventional, and non-conventional organic pollutants would be mass-based.

Permit writers should use a reasonable estimate of process wastewater discharge flow, allowing for no more than 25% nonprocess wastewater flow, and the concentration-based standards listed in Tables 16-3 and 16-4 to develop mass-based permit limitations for the NPDES permit. Section 15.3.3 presents guidance regarding how a reasonable estimate of process wastewater discharge flow should be established. Additional detailed guidance on establishing permit limitations is available in the Guidance for Implementing the Pharmaceutical Manufacturing Industry Regulations.

EPA expects permit limitations for cyanide at in-plant locations based on the 1983 NSPS limitations should be concentration-based, and would not be converted to a mass basis. A concentration basis offers a direct benchmark to assess whether the in-plant control technology is achieving the intended NSPS level. In-plant wastestreams that require control may be generated or treated on a variable, batch basis. In such a setting, mass-based permit limitations are difficult to establish accurately, hindering compliance because a direct measurement of the control technology performance cannot be made. Concentration-based permit limitations eliminate these problems and offer a direct measure of cyanide to both the permitting authority and the permitted facility that NSPS performance levels are being achieved.

16.3.4 Monitoring and Compliance

Compliance monitoring for the NSPS pollutants should be performed on a frequency basis established by the permit authority. EPA's monitoring costs for this regulation assume compliance monitoring for ammonia and all regulated organic constituents on a weekly basis for Subcategory A and C facilities and monitoring for BOD₅, COD, and TSS on a daily basis for Subcategory A, B, C, and D facilities. The list of pollutants which require monitoring includes all regulated constituents listed in Table 16-1 for A/C Subcategory facilities, or Table 16-2 for B/D Subcategory facilities, generated or used in pharmaceutical manufacturing processes at the facility. Under the NSPS, monitoring for BOD₅, COD, TSS, pH, ammonia, and organic constituents generated or used in pharmaceutical manufacturing processes would occur at the point of discharge to waters of the United States and before dilution with significant amounts of nonprocess waters.

Compliance with mass-based permit limitations is determined by multiplying the measured concentration of a regulated pollutant in the effluent sample by a conversion factor and by the total wastewater flow at the monitoring location during the effluent sampling period. Thus, the mass compliance value should be based on the total flow discharged on the day of sampling, not on the long-term average process water flow rate that provided the basis for establishing the permit limitations and standards.

Monitoring for cyanide for Subcategories A and C would be performed in-plant, prior to commingling or dilution with non-cyanide-bearing wastewater, unless a facility can show end-of-pipe monitoring for cyanide is feasible. To show that end-of-pipe monitoring is feasible, the facility would need to demonstrate compliance with cyanide limitations, adjusted as necessary to account for dilution with non-cyanide-bearing wastewater, at a level above the detection limit.

The list of pollutants for which EPA proposes to require monitoring should be updated based on consideration of raw material and process changes throughout the facility and an annual scan for all pollutants in Table 16-1 for Subcategory A/C facilities. The annual scan should be performed at the compliance monitoring point(s) to identify any regulated pollutants in the wastewater.

Permit monitoring and compliance should be required at all monitoring locations for all pollutants detected at any locations.

Dischargers must use the test methods promulgated at 40 CFR Part 136.3 or incorporated by reference in the tables of that part, when available, to monitor pollutant discharges from the pharmaceutical manufacturing industry, unless specified otherwise in part 439 (see 40 CFR 401.13) or by the permitting authority.

As a part of the final rule, EPA promulgated additional test methods for the pollutants to be regulated under Part 439 for which there are no test methods listed at 40 CFR Part 136.3. To support the Part 439 regulations at the time of proposal, EPA published test methods developed specifically for the pharmaceutical industry in a compendium entitled, “Analytical Methods for the Determination of Pollutants in Pharmaceutical Manufacturing Industry Wastewater,” EPA-821-B-94-001. These test methods were discussed in the proposed rule and have been revised in response to public comment. The revised test methods are available for monitoring some pollutants covered by today’s final rule. The revised test methods have been published in a revised compendium (the “Pharmaceutical Methods Compendium, Revision A;” EPA-821-B-98-016, 1998), with the same title as the proposed compendium.

In addition, EPA is allowing use of applicable drinking water methods that have been promulgated at 40 CFR Part 141 and use of ASTM Methods D3371, D3695, and D4763, for monitoring of the pollutants included in this rulemaking. The final rule allows for use of these additional test methods for several reasons: (1) it allows greater flexibility in monitoring; (2) it conforms use of methods in EPA’s drinking water and wastewater programs; (3) it moves toward a performance-based measurement system; and (4) it allows use of technical standards as contemplated by the National Technology Transfer and Advancement Act of 1995 (NTTAA).

Table 16-1

Pollutants Regulated Under NSPS for Subcategory A and C Facilities

Conventional Pollutants	
BOD ₅	TSS
Priority Pollutants	
Benzene	1,2-Dichloroethane
Chlorobenzene	Methylene chloride
Chloroform	Phenol
o-Dichlorobenzene (1,2-Dichlorobenzene)	Toluene
Cyanide ^(a)	
Nonconventional Pollutants	
Ammonia	n-Hexane
COD (Chemical Oxygen Demand)	Isobutyraldehyde
Acetone	Isopropanol
Acetonitrile	Isopropyl acetate
n-Amyl acetate	Isopropyl ether
Amyl alcohol	Methanol
n-Butyl acetate	Methyl cellosolve
Diethylamine	Methyl formate
Dimethyl Sulfoxide	Methyl isobutyl ketone (MIBK)
Ethanol	Tetrahydrofuran
Ethyl acetate	Triethylamine
n-Heptane	Xylenes

(a) Retaining cyanide effluent limits established in the 1983 final rule.

Table 16-2

Pollutants Regulated Under NSPS for Subcategory B and D Facilities

Conventional Pollutants	
BOD ₅	TSS
Nonconventional Pollutants	
COD (Chemical Oxygen Demand)	

Table 16-3

NSPS for Subcategory A and C Operations

Pollutant or Pollutant Property	NSPS for In-Plant Monitoring Points	
	Maximum for any 1 day mg/L	Monthly Average mg/L
Cyanide ^(a)	33.5	9.4

(a) Cyanide effluent limit established in the 1983 Final Rule.

Pollutant or Pollutant Property	NSPS for End-of-Pipe Monitoring Points	
	Maximum for any 1 day mg/L	Monthly Average mg/L
BOD ₅	267	111
COD	1,675	856
TSS	472	166

Pollutant or Pollutant Property	NSPS for End-of-Pipe Monitoring Points	
	Maximum for any 1 day mg/L	Monthly Average mg/L
Ammonia as N	84.1	29.4
Acetone	0.5	0.2
Acetonitrile	25.0	10.2
n-Amyl Acetate	1.3	0.5
Amyl Alcohol	10.0	4.1
Benzene	0.05	0.02
n-Butyl Acetate	1.3	0.5
Chlorobenzene	0.15	0.06
Chloroform	0.02	0.01
o-Dichlorobenzene	0.15	0.06
1,2-Dichloroethane	0.4	0.1
Diethylamine	250.0	102.0
Dimethyl Sulfoxide	91.5	37.5
Ethanol	10.0	4.1
Ethyl Acetate	1.3	0.5
n-Heptane	0.05	0.02
n-Hexane	0.03	0.02
Isobutyraldehyde	1.2	0.5

Table 16-3 (Continued)

Pollutant or Pollutant Property	NSPS for End-of-Pipe Monitoring Points	
	Maximum for any 1 day mg/L	Monthly Average mg/L
Isopropanol	3.9	1.6
Isopropyl Acetate	1.3	0.5
Isopropyl Ether	8.4	2.6
Methanol	10.0	4.1
Methyl Cellosolve	100.0	40.6
Methylene Chloride	0.9	0.3
Methyl Formate	1.3	0.5
MIBK	0.5	0.2
Phenol	0.05	0.02
Tetrahydrofuran	8.4	2.6
Toluene	0.06	0.02
Triethylamine	250.0	102.0
Xylenes	0.03	0.01

Table 16-4

NSPS for Subcategory B and D Operations

Pollutant or Pollutant Property	NSPS for End-of-Pipe Monitoring Points	
	Maximum for any 1 day mg/L	Monthly Average mg/L
BOD ₅	35	18
COD	228	86
TSS	58	31

Table 16-5

Surrogates for Subcategory A/C Direct Dischargers (Biotreatment)

Group	Compound	Surrogate (yes/no)
Alcohols	Ethanol	Yes
	Isopropanol	Yes
	Methanol	Yes
	Phenol	No
	Amyl alcohol	No
Aldehydes	Isobutyraldehyde	No
Alkanes	n-Heptane	Yes
	n-Hexane	Yes
Amides & Amines	Triethylamine	No
	Diethylamine	No
Aromatics	Toluene	Yes
	Xylenes	Yes
	Chlorobenzene	No
	o-Dichlorobenzene	No
	Benzene	No
Chlorinated Alkanes	Methylene chloride	Yes
	Chloroform	Yes
	1,2-Dichloroethane	Yes
Esters & Ethers	Ethyl acetate	Yes
	Tetrahydrofuran	Yes
	Isopropyl acetate	No
	n-Amyl acetate	No
	Isopropyl ether	No
	n-Butyl acetate	No
	Methyl formate	No
Ketones	Acetone	Yes
	MIBK	No
Miscellaneous	Ammonia (aqueous)	No
	Acetonitrile	No
	Dimethyl sulfoxide	No
	Methyl cellosolve	No

Yes-Surrogate pollutant for that group

No-Not a surrogate pollutant for that group

REFERENCES

1. U.S. EPA, Office of Water. Statistical Support Document for the Effluent Limitations Guidelines for the Pharmaceutical Manufacturing Industry EPA-821-B-98-002. U.S. Environmental Protection Agency, Washington, D.C., 1998.