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PROPOSED DEVELOPMENT DOCUMENT

FOR

NEW SOURCE PERFORMANCE STANDARDS

FOR THE

PHARMACEUTICAL MANUFACTURING

POINT SOURCE CATEGORY

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SECTION I

CONCLUSIONS

GENERAL

The Environmental Protection Agency (EPA) is proposing regulations that would limit the discharge of five-day biochemical oxygen demand (BOD5) and total suspended solids (TSS) into waters of the United States by new sources in four subcategories of the pharmaceutical manufacturing point source category. This document addresses new source performance standards (NSPS) for conventional pollutants required under the Clean Water Act.

NEW SOURCE PERFORMANCE STANDARDS (NSPS)

The technology basis of proposed NSPS for control of BOD5 and TSS is advanced biological treatment (i.e., biological treatment with longer detention time than considered as the basis of best practicable control technology currently available (BPT)) in combination with effluent filtration. Proposed NSPS are shown in Table I-1.

TABLE I-1

PROPOSED CONVENTIONAL POLLUTANT NSPS
FOR THE
PHARMACEUTICAL MANUFACTURING POINT SOURCE CATEGORY

	Pollutant			
	BOD_5		TSS	
Subcategory	Maximum 30-Day Average	Daily Maximum	Maximum 30-Day Average	Daily Maximum
A-Fermentation	76.8 mg/l	115.0 mg/l	193.0 mg/l	491.0 mg/l
B-Extraction	11.2 mg/l	40.7 mg/l	26.5 mg/l	58.9 mg/l
C-Chemical Synthesis	76.8 mg/l	115.0 mg/l	193.0 mg/l	491.0 mg/l
D-Mixing/Compounding and Formulation	11.2 mg/l	40.7 mg/l	26.5 mg/l	58.9 mg/l

SECTION II

INTRODUCTION

PURPOSE AND AUTHORITY

The Federal Water Pollution Control Act Amendments of 1972 (P.L. 92-500; the Act) established a comprehensive program to "restore and maintain the chemical, physical, and biological integrity of the Nation's waters" (see Section 101(a)). New industrial direct dischargers were required to comply with new source performance standards (NSPS), established under authority of Section 306, based on the best available demonstrated technology.

Although Section 402(a)(1) of the 1972 Act authorized the setting of requirements for direct dischargers on a case-by-case basis in the absence of regulations, Congress intended that, for the most part, control requirements would be based on regulations promulgated by the Administrator of EPA. Sections 304(c) and 306 of the Act required promulgation of regulations for NSPS. Section 501(a) of the Act authorized the Administrator to prescribe any additional regulations "necessary to carry out his functions" under the Act.

As a result of the Settlement Agreement in Natural Resources Defense Council, Inc, v. Train, 8 ERC 2120 (D.D.C. 1976), modified, 12 ERC 1833 (D.D.C. 1979), modified by Orders dated October 26, 1982, and August 2, 1983, the Clean Water Act was amended in 1977 to strengthen the Agency's toxic pollutant control programs. The Settlement Agreement did not impact NSPS for conventional pollutants.

SCOPE OF THIS RULEMAKING

On November 26, 1982, EPA proposed regulations applicable to the pharmaceutical manufacturing point source category (47 FR 53584). At that time, EPA (a) proposed to modify the existing BPT TSS effluent limitations for three subcategories (subcategory B--extraction products, subcategory D--mixing/compounding and formulation, and subcategory E--research), (b) proposed BPT TSS effluent limitations for two subcategories (subcategory A--fermentation products, and subcategory C--chemical synthesis products, (c) proposed to modify the existing BPT effluent limitations for BOD_5 and COD for subcategories A, B, C, D, and E, (d) proposed BPT and BAT effluent limitations, NSPS, PSES, and PSNS for cyanide to apply uniformly to subcategories A, B, C, and D, (e) proposed BAT limitations and NSPS for chemical oxygen demand (COD) to apply uniformly to subcategories A, B, C, and D, (f) proposed BCT effluent limitations for BOD_5, TSS, and pH to apply uniformly to subcategories A, B, C, and D, and (g) proposed NSPS for BOD_5, TSS, and pH to apply uniformly to subcategories A, B, C, and D, based on the application of advanced biological treatment (i.e., biological treatment systems with longer detention times than those considered as the basis of effluent limitations reflecting the best practicable control technology currently available (BPT)).

Simultaneously with publication of this proposed development document, the Agency is promulgating regulations covering most aspects of the November 1982 proposal. In brief, EPA is promulgating BPT effluent limitations for TSS for subcategories A and C and is modifying existing BPT BOD5, COD, and TSS effluent limitations for subcategories B, D, and E. The Agency is also establishing BPT and BAT effluent limitations guidelines, NSPS, PSES, and PSNS controlling cyanide discharges from pharmaceutical plants in subcategories A, B, C, and D. EPA has not addressed best conventional pollutant control technology (BCT) because the BCT methodology has not yet been issued. The BCT methodology and BCT limitations for the pharmaceutical industry will be published at a later date. EPA also has not promulgated final BAT effluent limitations and NSPS for COD because the Agency needs more information on the identity of pollutants that contribute to COD and on applicable COD removal technologies.

The remaining issue to be addressed is NSPS for conventional pollutants. In commenting on the November 1982 proposal, the industry complained that new sources in subcategories A and C could not meet the proposed NSPS because the Agency's proposed subcategorization scheme was incorrect and because the data base used to develop proposed NSPS contained too many low raw waste load (subcategory D) facilities. They also contended that percent reduction-based standards are more appropriate than concentration-based standards because of the wide variation in the raw waste characteristics of pharmaceutical plant discharges.

The Agency's review of the data used to develop the November 1982 proposed NSPS indicated that subcategory D plants did indeed dominate the data base. EPA analyzed all available data, including new data submitted with comments, and found that fermentation (subcategory A) and chemical synthesis (subcategory C) plants have higher conventional pollutant raw waste loads than extraction (subcategory B) and formulation (subcategory D) plants. (See Section IV of the Development Document for Effluent Guidelines, New Source Performance Standards, and Pretreatment Standards for the Pharmaceutical Manufacturing Point Source Category (U.S. EPA, September 1983), hereafter, "final development document). (1) Additionally, the Agency was aware that permitting authorities and the regulated industry were familiar with the original subcategorization scheme and the format of the Code of Federal Regulations. Therefore, as explained more fully in the final development document, EPA decided to maintain the original BPT subcategorization scheme.

After proposal, EPA identified four pharmaceutical plants which added effluent filtration systems to advanced biological treatment systems. Conventional pollutant discharges from these plants are significantly lower than from plants where only advanced biological treatment is employed. Consequently, the Agency believes that the addition of effluent filtration to advanced biological treatment is a technology option which must be considered in establishing NSPS for conventional pollutants in this industry.

The public had not yet had an opportunity to provide comments on Agency estimates of the costs of the addition of effluent filtration or on the additional effluent reduction benefits of filtration technology when applied at new source pharmaceutical plants. Therefore, EPA determined that it would be appropriate to propose rather than promulgate NSPS for conventional pollutants based on this model treatment technology. After reviewing all available data, as explained in Section VII, EPA determined that effluent filtration is the appropriate technology basis of NSPS and decided to propose NSPS based on the combination of advanced biological treatment and effluent filtration.

The Agency continues to believe that concentration-based standards are appropriate as the basis for NSPS in the pharmaceutical industry. Available data on the application of advanced biological treatment and effluent filtration indicate that industry is capable of designing and operating end-of-pipe treatment systems that will achieve the concentration-based standards specified in Sections I and VII of this document.

SUMMARY OF METHODOLOGY

EPA's implementation of the Act required a complex development program, described in detail in the Proposed Development Document for Effluent Limitations Guidelines and Standards for the Pharmaceutical Point Source Category (U.S. EPA, November 1982), hereafter, proposed development document.(2) First, EPA studied the pharmaceutical industry to determine the impact of raw material usage, final products manufactured, process equipment, size and age of manufacturing facilities, water use, and other factors on the level of conventional pollutants discharged from plants in this industry. This required the identification of raw waste and final effluent characteristics, including the sources and volumes of water used, the manufacturing processes employed, and the sources of pollutants and wastewaters within the facility.

EPA then identified all subcategories for which NSPS should be proposed. The Agency characterized the raw waste conventional pollutant discharges from plants in these subcategories. Next, EPA identified several distinct control and treatment technologies which are in use or capable of being used to control conventional pollutants in pharmaceutical industry wastewaters. The Agency compiled and analyzed historical and newly-generated data on effluent quality resulting from the application of these technologies. The long-term performance, operational limitations, and reliability of each of the treatment and control technologies were also identified. In addition, EPA considered the non-water quality environmental impacts of these technologies, including impacts on air quality, solid waste generation, and energy requirements.

The Agency then estimated the costs for each control and treatment technology from unit cost curves developed by standard engineering analysis as applied to the specific pharmaceutical industry wastewater

characteristics. EPA derived unit process costs from model plant characteristics (flow, pollutant raw waste loads) applied to each treatment process unit cost curve (i.e., primary clarification, activated sludge, filtration). These unit process costs were combined to yield the total installed equipment cost at each treatment level. Total capital costs were then derived from the installed equipment costs. After confirming the reasonableness of these cost estimates, the Agency evaluated the economic impacts of these costs. The economic analysis is the subject of another document: Economic Analysis of Effluent Standards and Limitations for the Pharmaceutical Industry (U.S. EPA, September 1983). (3)

Upon consideration of these factors, EPA identified the combination of control and treatment technologies that reflect the best available demonstrated technology (NSPS). The proposed regulations, however, do not require installation of any particular combination of technologies. Rather, they require achievement of effluent limitations representative of the proper application of these technologies or equivalent technologies.

SECTION III

DESCRIPTION OF THE INDUSTRY

INTRODUCTION

Pharmaceutical plants manufacture biological products, medicinal chemicals, botanical products, and other pharmaceutical products. EPA identified 466 operating facilities involved in the manufacture of pharamceutical products. Most of the pharmaceutical industry is located in the eastern half of the United States. The most prevalent manufacturing operation in the industry is the formulating, mixing, and compounding operation; batch-type production is the most common type of manufacturing technique for this industry.

The wastewaters produced and discharged by the pharmaceutical industry are very diverse. Plant size, products, processes, and materials to which wastewater is exposed vary greatly. Additionally, the ratio of finished product to the quantity of raw materials, solvents, and other processing materials is generally very low. A detailed discussion of the pharmaceutical industry is included in Section III of the final development document and in Section III of the proposed development document.(1)(2)

SUBCATEGORIZATION

As described in Section II of this document, the Agency is maintaining the original BPT subcategorization scheme, under which the pharmaceutical manufacturing industry was segmented into the following five subcategories:

Subcategory A: Fermentation Products

Subcategory B: Extraction Products

Subcategory C: Chemical Synthesis Products

Subcategory D: Mixing/Compounding and Formulation

Subcategory E: Research

A detailed description of the manufacturing processes and raw materials used in each of these subcategories is presented in Sections III and IV of the proposed development document and in the final development document.

EPA is not proposing NSPS for the research subcategory (Subcategory E) because pharmaceutical research does not involve production, nor does research generate wastewater in appreciable quantities on a regular basis. Additionally, pharmaceutical research is not mentioned in the

Settlement Agreement. For these reasons, EPA focused its studies on the four production subcategories.

As discussed in Section II of this document, commenters on the November 1982 proposed NSPS contended that different standards should apply to high raw waste load plants in subcategories A and C than to low raw waste load plants in subcategories B and D. Some commenters submitted new data to support their contentions. EPA added these new data to the existing data base.

The Agency's analyses of the most recent data, including the new data submitted with comments, indicate that the subcategorization scheme for this industry should separate fermentation and chemical synthesis plants (subcategory A and C plants) from extraction and formulation plants (subcategory B and D plants). Specifically, EPA's analyses show that usually the influent and effluent conventional pollutant concentrations and discharge flows of subcategory A and C plants are similar. The Agency also found that these characteristics for subcategory B and D plants are similar. However, EPA found that the characteristics of the subcategory A and C plant group are not similar to the corresponding characteristics of the subcategory B and D plant group. Because conventional pollutant raw waste characteristics are similar for subcategory A and C plants, the Agency believes that conventional pollutant NSPS for those plants should be identical. For the same reason, conventional pollutant NSPS for subcategory B plants should be identical to those for subcategory D plants.

EXISTING END-OF-PIPE TREATMENT AT PHARMACEUTICAL PLANTS

Table III-1 presents information on the methods of wastewater discharge employed at the 466 pharmaceutical manufacturing plants in the Agency's data base. At 12 percent of the plants, wastewater is treated on-site in a treatment system operated by plant personnel and discharged directly to waters of the United States. At 59 percent of the pharmaceutical facilities, wastewater is discharged to a publicly owned treatment works (POTW). At 29 percent of the pharmaceutical plants, wastewater is not generated or all of the wastewater that is generated is not discharged to navigable waters.

Table III-2 presents information on the types of treatment currently in-place at direct discharging pharmaceutical plants. Seventy-five percent of the direct discharging plants in the industry utilize biological treatment, and 16 percent of the direct discharging plants employ filtration systems in addition to biological treatment.

TABLE III-1

SUMMARY OF METHOD
OF DISCHARGE AT
PHARMACEUTICAL PLANTS

Method of Discharge	No. of Plants
Direct Dischargers	55
Indirect Dischargers	277
Zero Dischargers	134
Total Plants	466

TABLE III-2

IN-PLACE TREATMENT TECHNOLOGY AT
DIRECT DISCHARGING PHARMACEUTICAL PLANTS

Treatment Technology	No. of Plants
Biological Treatment	38
Biological Treatment Plus Filtration	8
Physical Chemical	3
Unknown	2
Total Plants	51*

* 4 direct discharging plants primarily produce products other than pharmaceuticals and, therefore, have not been included in the data base.

SECTION IV

WASTE CHARACTERIZATION

INTRODUCTION

The Agency conducted an extensive data gathering effort and developed qualitative and quantitative information on the characteristics of the wastewaters discharged by the pharmaceutical industry. This section summarizes available information on the characteristics of raw waste and final effluent discharges from direct discharging pharmaceutical plants. Only conventional pollutant data are presented in this document.

WASTE CHARACTERIZATION

Table IV-1 presents a summary of available raw waste and final effluent BOD5 and TSS data for direct discharging pharmaceutical plants.

DEVELOPMENT OF MODEL PLANT RAW WASTE CHARACTERISTICS

As shown in Table IV-1, EPA was able to determine applicable long-term average BPT BOD5 and TSS effluent levels for 27 of the 51 direct discharging plants in the Agency's data base. The Agency identified best performing plants by comparing actual effluent levels of BOD5 and TSS discharged from pharmaceutical plants to the long-term average BOD5 and TSS levels that form the basis of BPT effluent limitations. EPA defined best performers as those plants that meet both the BPT BOD5 and TSS effluent levels.

Plants 11111, 12022, 12026, 12036, 12132, 12161, 12236, 33333, and 55555 are best performing subcategory A and C plants employing biological treatment; plant 12161 also employs effluent filtration in combination with biological treatment to effect a further removal of BOD5 and TSS. As explained in the footnotes on Table IV-1, at present, sufficient data are not available for plants 11111, 33333, and 55555 to characterize properly their final effluent BOD5 and TSS concentrations. Plants 12015, 12053, 12117, 12317, 12459, 12463, and 44444 are best performing subcategory B and D plants. Plants 12015, 12117, 12459, and 12463 employ biological treatment; plants 12053, 12317, and 44444 employ effluent filtration technology in combination with biological treatment.

Tables IV-2, IV-3, and IV-4 present raw waste characteristics of subcategory A and C best performers for which sufficient data are available to characterize properly their final effluent characteristics, of subcategory B and D best performers employing biological treatment, and of subcategory B and D best performers employing effluent filtration, respectively.

TABLE IV-1

RAW WASTE AND FINAL EFFLUENT CHARACTERISTICS OF DIRECT DISCHARGING PHARMACEUTICAL PLANTS

Plant	Subcategory	Treatment	Flow (MGD)	R.W. BOD_5 (mg/l)	R.W. TSS (mg/l)	LTA BPT BOD_5 (mg/l)	LTA BPT TSS (mg/l)	LTA Eff. BOD_5 (mg/l)	LTA Eff. TSS (mg/l)
11111*	C	1	0.042	2733.1	-	273.3	464.6	164.5	385.0
12001	D	1	0.140	-	-	-	-	21.0	-
12006	D	0	0.001	-	-	-	-	-	-
12014	B	1	0.387	-	-	-	-	-	-
12015	D	1	0.101	232.6	123.8	23.3	39.6	9.7	10.8
12022	A,C	1	1.448	2141.6	-	214.2	364.1	110.2	84.9
12026	C	1	0.161	3670.0	87.9	367.0	623.9	108.1	283.7
12036	A	1	1.092	1570.8	1059.1	157.1	267.1	33.0	78.1
12038	A,B,C,D	1	8.316	662.0	-	66.2	112.5	28.3	17.9
12053	D	2	2.500	299.0	383.0	29.9	50.8	8.0	2.0
12073	C	0	0.015	-	-	-	-	-	-
12085	D	1	0.001	-	-	-	-	32.2	29.6
12089	B,D	1	0.350	-	-	-	-	13.0	13.0
12095	C,D	3	0.174	-	133.0	-	-	-	6.2
12097	C,D	3	0.064	1577.3	-	157.7	268.1	49.5	18.1
12098	D	1	0.006	-	-	-	-	409.9	392.1
12104	D	1	2.200	-	-	-	-	-	-
12117	B,D	1	0.101	34.5	-	15.0	25.5	1.9	16.0
12119	A,D	1,3	0.064	-	-	-	-	7.3	70.2
12132	A,C	1	0.981	3000.0	1150.0	300.0	510.0	68.6	452.9
12160	D	2,3	0.029	490.2	1615.2	49.0	83.3	166.9	115.4
12161	A,C,D+	2	1.925	1361.6	421.7	136.2	231.5	19.8	31.6
12187	C	1	-	-	-	-	-	707.3	60.5
12205	D	2	0.036	-	-	-	-	60.0	40.0

TABLE IV-1
(Continued)

Plant	Subcategory	Treatment	Flow (MGD)	R.W. BOD_5 (mg/l)	R.W. TSS (mg/l)	LTA BPT BOD_5 (mg/l)	LTA BPT TSS (mg/l)	LTA Eff. BOD_5 (mg/l)	LTA Eff. TSS (mg/l)
12236	C	1	1.007	1652.0	-	165.2	280.8	155.6	108.3
12248	D	1	0.110	294.0	-	29.4	50.0	26.0	60.5
12256	A,B,C,D	3	-	-	-	-	-	-	-
12283	D	1	0.025	-	-	-	-	35.0	50.0
12287	D	1	0.430	-	-	-	-	-	13.0
12294	C,D	1	0.118	1584.3	-	158.4	269.3	44.7	13.0
12298	D	1	0.007	-	-	-	-	15.0	26.0
12307	D	1	0.002	-	-	-	-	11.4	32.3
12308	D	1	0.032	130.0	67.0	15.0	25.5	-	-
12317	D	2,3	0.740	1003.7	41.4	100.4	170.7	7.9	9.8
12338	D	2	0.004	200.0	200.0	20.0	34.0	30.0	30.0
12406	C	3	0.994	-	420.0	-	-	-	10.0
12459	D	1	0.049	69.5	58.6	15	25.5	3.8	16.7
12462	A	1	0.153	1765.4	987.3	176.5	300.1	117.5	582.3
12463	B,D	1,3	0.056	102.0	-	15	25.5	5.7	9.6
12471	B	1	0.103	50.0	-	15	25.5	14.0	59.0
20037	D	1	0.037	-	-	-	-	20.0	47.0
20165	B,C	1	0.004	123.0	-	15.0	25.5	25.0	16.0
20201	D	1	0.002	-	14.0	-	-	6.0	-
20246	C	2	1.590	-	-	-	-	13.0	33.0
20257	C	1	0.107	484.0	-	48.4	82.3	143.0	74.0
20298	C	1	0.001	-	-	-	-	-	-
20319	D	1,3	0.052	-	-	-	-	15.0	8.5

TABLE IV-1
(Continued)

Plant	Subcategory	Treatment	Flow (MGD)	R.W. BOD_5 (mg/l)	R.W. TSS (mg/l)	LTA BPT BOD_5 (mg/l)	LTA BPT TSS (mg/l)	LTA Eff. BOD_5 (mg/l)	LTA Eff. TSS (mg/l)
20370	B,C	1	0.014	-	-	-	-	-	-
33333*	C	1	0.124	3115.2	725.7	311.5	529.6	121.0	212.0
44444**	D	2	0.016	333.0	270.0	33.3	56.6	3.0	9.8
55555***	C	1	0.144	2949.0	423.0	294.9	501.3	78.5	62.0

Treatment Codes

0 = No Treatment Reported
1 = Biological Treatment
2 = Biological Treatment + Effluent Filtration
3 = Physical Chemical Treatment

Abbreviations and Notations

R.W. = Raw Waste
LTA = Long-Term Average
* = Data reported covers less than 6 months period.
** = Data reported covers less than 12 months period.
\+ = D subcategory operations contribute approximately 2% of total process flow.
\- = No data supplied
*** = Data reported covers less than 12 month period and does not cover a consecutive 6 month period.

TABLE IV-2

RAW WASTE CHARACTERISTICS OF SUBCATEGORY A AND C BEST PERFORMERS

Plant	Subcategory	Raw Waste Characteristics Flow (MGD)	BOD_5 (mg/l)	TSS (mg/l)
12022	A, C	1.448	2142	N.A.
12026	C	0.161	3670	88
12036	A	1.092	1571	1059
12132	A, C	0.981	3000	1150
12161	A, C, D*	1.925	1362	422
12236	C	1.007	1652	N.A.
Average		1.078	2233	680

N.A. = Not available

*About 2 percent of the total wastewater discharge flow results from formulation operations.

TABLE IV-3

RAW WASTE CHARACTERISTICS OF SUBCATEGORY B AND D
BEST PERFORMERS EMPLOYING BIOLOGICAL
TREATMENT

Plant	Subcategory	Raw Waste Characteristics Flow (MGD)	BOD_5 (mg/l)	TSS (mg/l)
12015	D	0.101	233	124
12117	B, D	0.101	35	N.A.
12459	D	0.049	70	59
12463	B, D	0.056	102	N.A.
Average		0.077	118*	103*

N.A. = Not available

*Flow-weighted average

TABLE IV-4

RAW WASTE CHARACTERISTICS OF SUBCATEGORY B AND D
BEST PERFORMERS EMPLOYING BIOLOGICAL
TREATMENT AND EFFLUENT FILTRATION

Plant	Subcategory	Raw Waste Characteristics Flow (MGD)	BOD_5 (mg/l)	TSS (mg/l)
12053	D	2.50	299	383
12317	D	0.74	1004	41.4
44444	D	0.016	333	270
Average		1.085	459*	305*

*Flow-weighted average

Subcategory A and C Plant Group

As shown in Table IV-2, plant 12161, the only best performing plant in the subcategory A and C group employing filtration technology, has relatively low raw waste BOD5 concentrations compared to the other subcategory A and C best performers. Rather than base model plant raw waste characteristics solely on this plant, EPA averaged the BOD5 and TSS raw waste concentrations for all six best performers to develop NSPS model plant raw waste characteristics. These are shown in Table IV-2. The BOD5 and TSS raw waste concentrations are 2230 mg/l and 680 mg/l, respectively.

Subcategory B and D Plant Group

By comparing Tables IV-3 and IV-4, it is apparent that flow-weighted average BOD5 and TSS raw waste concentrations at best performing subcategory B and D plants employing biological treatment are considerably lower than for best performers employing biological treatment and effluent filtration. EPA averaged the BOD5 and TSS raw waste concentrations for the best performing plants employing filtration in combination with biological treatment to develop the model new source subcategory B and D plant. This ensures that the entire range of raw waste BOD5 concentrations that exist within the B and D subcategories are represented by the model plant. The model new source subcategory B and D BOD5 and TSS raw waste concentrations are 459 mg/l and 305 mg/l, respectively, as shown on Table IV-4.

Summary

Table IV-5 presents the BOD5 and TSS raw waste characteristics for the new source model plants representative of the subcategory A and C and the subcategory B and D plant groups. Estimates of the cost of the application of conventional pollutant control options and of the non-water quality implications of these options are based, in part, on these raw waste characteristics.

TABLE IV-5

NEW SOURCE MODEL PLANT
RAW WASTE CHARACTERISTICS

	Raw Waste Characteristics (mg/l)	
	BOD_5	TSS
Subcategory A and C Plant Group	2233	680
Subcategory B and D Plant Group	459	305

SECTION V

DEVELOPMENT OF CONTROL AND TREATMENT OPTIONS

INTRODUCTION

The basis for new source performance standards (NSPS) under Section 306 of the Act is the best available demonstrated technology. At new plants, the opportunity exists to design the best and most efficient pharmaceutical manufacturing and wastewater treatment technologies. Therefore, Congress directed EPA to consider the best demonstrated process changes, in-plant controls, and end-of-process treatment technologies that reduce pollution to the maximum extent feasible. As a result, limitations for NSPS should represent the most stringent numerical values attainable through the application of demonstrated control technology for all pollutants (conventional, nonconventional, and toxic).

As explained in Section II, after proposal, EPA identified four pharmaceutical plants which have added filtration systems to advanced biological treatment systems to control further the discharge of the conventional pollutants BOD5 and TSS. As shown in Table IV-1, conventional pollutant discharges from these plants are significantly lower than from plants where only advanced biological treatment is employed. Consequently, the Agency believes that the addition of filtration to advanced biological treatment is a technology option which must be considered in establishing NSPS for conventional pollutants in this industry. Therefore, in addition to the technology option that formed the basis of the November 1982 proposed NSPS (i.e., advanced biological treatment), EPA considered a second option -- effluent filtration in combination with advanced biological treatment -- as a possible basis for NSPS controlling conventional pollutant discharges from new source pharmaceutical plants.

CONTROL AND TREATMENT OPTIONS

In Section IV, data are presented on the actual conventional pollutant removals that are being acheived at individual direct discharging pharmaceutical plants. In addition to these data, EPA received data for one pharmaceutical plant, plant 12161, that can be used to estimate the BOD5 and TSS removal that occurs through the application of filtration technology subsequent to advanced biological treatment. These data are summarized in Table V-1. EPA's analysis of these data indicates that about 5.5 percent BOD5 removal and 29.2 percent TSS removal is achieved at plant 12161 through the application of effluent filtration technology. EPA relied on the data presented in Table IV-1 and in Table V-1 to determine the conventional pollutant removal capabilities of the two technology options considered for control of BOD5 and TSS at new source direct discharging pharmaceutical plants.

[NOTE: In the preamble to the 1983 proposed NSPS for BOD5 and TSS, EPA is requesting additional data on the conventional pollutant removal

TABLE V-1

CONVENTIONAL POLLUTANT REMOVAL AT PLANT 12161
THROUGH THE APPLICATION OF EFFLUENT FILTRATION TECHNOLOGY

	No. of Observations		Long-Term Average Effluent Characteristics (mg/l)	
	BOD_5	TSS	BOD_5	TSS
Long-term Average Biological Treatment Effluent (mg/l)[1]	90	157	26.08[2]	37.07[2]
Long-term Average Filtration Effluent (mg/l)	191	319	24.64[3]	26.25[3]
Pollutant Removal Through Application of Filtration	-	-	5.5%	29.2%

[1]Estimated filtration influent, based on final effluent values prior to installation of the filtration system.

[2]Data are for the period 1/1/80 to 7/31/80; raw waste BOD_5 was 1279 mg/l during that timeframe.

[3]Data are for the period 8/1/80 to 12/31/81; raw waste BOD_5 was 1402 mg/l during that timeframe.

capability of filtration technology when applied to pharmaceutical effluents from biological treatment systems. EPA intends to use these data to confirm the accuracy of the conventional pollutant removals shown in Table V-1.]

NSPS Option A

Base NSPS controlling BOD5 and TSS on the performance of the best plants employing advanced biological treatment. This option is identical to the technology option selected for the November 1982 proposal. This would require that specific concentration-based limits be met. Standards for extraction (subcategory B) and formulation (subcategory D) plants would be identical. Standards for fermentation plants (subcategory A) would be the same as those for chemical synthesis plants (subcategory C).

Tables V-2 and V-3 present long-term average final effluent BOD5 and TSS concentrations discharged from best performing pharmaceutical plants employing advanced biological treatment in the subcategory A and C plant group and in the subcategory B and D plant group, respectively. For the subcategory A and C plant group, EPA expects the application of NSPS Option A to attain long-term average BOD5 and TSS discharge levels of 70.1 and 130.1 mg/l, respectively. These values are the weighted averages of the individual plant data presented in Table V-2, weighted based on the number of data points available for each plant.

As explained in Section IV, the best performing subcategory B and D plants employing advanced biological treatment have significantly lower raw waste BOD5 concentrations than the subcategory B and D plants employing effluent filtration in addition to advanced biological treatment. Because the subcategory B and D plants employing advanced biological treatment are not representative of the entire range of raw waste BOD5 concentrations that exist in subcategories B and D, EPA did not base its assessment of the removal capability of NSPS Option A on the data in Table V-3. Rather, EPA determined the attainable long-term average BOD5 and TSS effluent concentrations achieved at subcategory B and D plants (BOD5 = 7.85 mg/l and TSS = 9.80 mg/l, based on the median level attained at subcategory B and D plants employing filtration in addition to advanced biological treatment; see Table V-4) and adjusted these concentrations based on the BOD5 and TSS removal that occurs through the application of filtration at plant 12161. This calculation yields long-term average effluent concentrations at subcategory B and D plants for NSPS Option A of:

BOD5 = (7.85 mg/l)/(1-0.055) = 8.31 mg/l

TSS = (9.80 mg/l)/(1-0.292) = 13.84 mg/l

EPA estimated conventional pollutant removals for new source plants having conventional pollutant raw waste concentrations equal to those for the model plants developed in Section IV. EPA estimates that a

TABLE V-2

FINAL EFFLUENT CHARACTERISTICS OF BEST
PERFORMING SUBCATEGORY A AND C
PHARMACEUTICAL PLANTS EMPLOYING
ADVANCED BIOLOGICAL TREATMENT

Plant	Subcategory	No. of Observations BOD_5	No. of Observations TSS	Long-Term Average Effluent Characteristics (mg/l) BOD_5	Long-Term Average Effluent Characteristics (mg/l) TSS
12022	A, C	392	395	110.24	84.85
12026	C	44	53	108.14	283.68
12036	A	366	364	33.04	78.12
12132	A, C	200	204	68.58	452.92
12161	A, C, D*	249	355	19.78	31.55
12236	C	105	105	155.60	108.25
NSPS Option A Long-Term Average Effluent Characteristics:				70.1**	130.0**

*About 2 percent of the total wastewater discharge flow results from formulation operations.

**Weighted average based on number of observations for each parameter at each plant.

TABLE V-3

FINAL EFFLUENT CHARACTERISTICS OF BEST PERFORMING SUBCATEGORY B AND D PHARMACEUTICAL PLANTS EMPLOYING ADVANCED BIOLOGICAL TREATMENT

Plant	Subcategory	No. of Observations BOD_5	No. of Observations TSS	Long-Term Average Effluent Characteristics (mg/l) BOD_5	Long-Term Average Effluent Characteristics (mg/l) TSS
12015	D	46	195	9.70	10.76
12117	B, D	39	51	1.94	16.00
12459	D	51	47	3.82	16.74
12463[1]	B, D	NA	NA	5.70	9.60
NSPS Option A Long-Term Average Effluent Characteristics:				8.31[2]	13.84[2]

[1]Only long-term average effluent concentrations are available for this plant, not individual data points.

[2]Based on adjusting effluent concentrations shown on Table V-4 for NSPS Option B by the BOD_5 and TSS removal that occurs at plant 12161. (See Table V-1.)

model new source A or C plant discharging 1.2 million gallons of wastewater per day (MGD), in complying with NSPS Option A, would remove 1.47 million pounds of BOD5 and TSS per year beyond that removed in complying with BPT. The Agency estimates that a model new source B or D plant discharging 0.050 MGD, in complying with NSPS Option A, would remove about 16,000 pounds of BOD5 and TSS per year beyond that removed in complying with BPT.

NSPS Option B

Base NSPS controlling BOD5 and TSS on the performance of the best plants employing advanced biological treatment in combination with effluent filtration. This would require that specific concentration-based limits be met. As with Option A, standards for subcategory B and D plants would be identical, and standards for subcategory A would be the same as those for subcategory C.

Table V-4 presents long-term average final effluent BOD5 and TSS concentrations discharged from pharmaceutical plants in the subcategory B and D plant group employing filtration in combination with advanced biological treatment. For the subcategory B and D plant group, EPA expects the application of NSPS Option B to attain long-term average BOD5 and TSS discharge levels of 7.85 mg/l and 9.80 mg/l, respectively. These values are the median long-term averages for the three subcategory B and D plants employing filtration technology. As shown on Table V-4, individual daily data are available for only one plant.

As shown in Table IV-1, at plant 12161, the only subcategory A and C plant employing both advanced biological treatment and filtration, BOD5 raw waste concentrations are in the low end of the range for all subcategory A and C plants. For this reason, EPA did not base its assessment of the removal capability of NSPS Option B solely on the effluent levels attained at plant 12161. Rather, EPA adjusted the attainable long-term average BOD5 and TSS effluent concentrations achieved at subcategory A and C plants through installation of advanced biological treatment (BOD5 = 70.1 mg/l and TSS = 130.0 mg/l; see Table V-2) based on the BOD5 and TSS removal that occurs through the application of filtration at plant 12161. This calculation yields long-term average effluent concentrations for NSPS Option B of:

$$BOD5 = (70.1 \text{ mg/l})(1-0.055) = 66.2 \text{ mg/l}$$

$$TSS = (130.0 \text{ mg/l})(1-0.292) = 92.1 \text{ mg/l}$$

EPA estimated conventional pollutant removals for new source plants having conventional pollutant raw waste concentrations equal to those for the model plants developed in Section IV. EPA estimates that a model new source A or C plant discharging 1.2 MGD, in complying with NSPS Option B, would remove 1.63 million pounds of BOD5 and TSS per year beyond that removed in complying with BPT. The Agency estimates that a model new source B or D plant discharging 0.050 MGD, in

TABLE V-4

FINAL EFFLUENT CHARACTERISTICS OF SUBCATEGORY B AND D PHARMACEUTICAL PLANTS EMPLOYING ADVANCED BIOLOGICAL TREATMENT AND EFFLUENT FILTRATION

Plant	Subcategory	No. of Observations BOD_5	No. of Observations TSS	Long-Term Average Effluent Characteristics (mg/l) BOD_5	Long-Term Average Effluent Characteristics (mg/l) TSS
12053[1]	D	N.A.	N.A.	8.00	2.00
12317	D	52	262	7.85	9.84
44444[1]	D	N.A.	N.A.	3.00	9.80
NSPS Option B Long-Term Average Effluent Concerntrations:				7.85	9.80

N.A. - Not Available

[1]Only long-term average effluent concentrations are available for this plant, not individual data points.

complying with NSPS Option B, would remove about 17,000 pounds of BOD5 and TSS per year beyond that removed in complying with BPT.

EFFLUENT VARIABILITY ANALYSIS

Introduction

The quantity of conventional pollutants discharged from wastewater treatment systems varies daily. EPA accounts for this variability in deriving standards limiting the amount of a pollutant that may be discharged. The statistical procedures used by EPA to analyze the variability of conventional pollutant discharges from the pharmaceutical industry are described below.

Daily Variability Factors

The daily variability factor is defined as the ratio of the estimated 99th percentile of the distribution of daily pollutant values to the estimated mean value of the distribution. For a specific pollutant discharged from a facility, EPA estimated the mean and 99th percentile from all daily effluent values which were not deleted on the basis of being erroneous or descriptive of aberrant performance.

In developing daily variability factors, the Agency considered both parametric (e.g., normal, lognormal) and nonparametric estimation procedures. In the course of examining the various parametric approaches and the data, it became apparent that no individual parametric distributional assumption would apply to all plant/pollutant data sets. For that reason, the Agency relied on a nonparametric procedure when enough daily data were available to apply the procedure and on a 2-parameter lognormal distribution when the amount of data was not sufficient to utilize the nonparametric procedure. Nonparametric procedures do not require satisfying assumptions on the form of the probability distribution of the underlying data. The specific nonparametric procedure has been used previously by the Agency to determine daily variability factors for other industries (e.g., BPT pesticide industry regulations). The lognormal distribution has also been used with effluent discharge data, because such data are generally skewed to a few large values and are bounded in the lower concentration range by zero. This dual approach provides a consistent methodology which minimizes the number of statistical assumptions required to analyze the data while utilizing as much plant data as possible for the treatment technologies of interest.

The nonparametric procedure estimates the 99th percentile from a set of daily discharge measurements by determining the smallest ordered discharge value in that set of values which is greater than or equal to the population 99th percentile with probability at least 0.5 (i.e., for a specified value of n, determine the smallest ordered value $X(j)$ such that $P[X(j) \geq \text{99th percentile}] = 1 - \sum_{i=j}^{n} \binom{n}{i} (.99)^i (.01)^{n-i} \geq .5)$.

The smallest ordered discharge value, satisfying this criterion, was determined by nonparametric methods (see, e.g., J.D. Gibbons, Nonparametric Statistical Inference, McGraw-Hill, 1971 (4)). An estimate chosen in this manner is sometimes referred to as a 50 percent reliable estimate, or 50 percent tolerance level, for the 99th percentile and is interpreted as the value below which 99 percent of the values of a future sample of size n will fall with probability criterion of at least 0.5. Therefore, the nonparametric procedure was applied only for plant/pollutant data sets with 69 or more observations. The arithmetic average of a facility's daily effluent values was used for the denominator of the nonparametric daily variability factor.

For plant/pollutant data sets with less than 69 daily observations, a 2-parameter lognormal distribution was used to estimate the 99th percentile and long-term average of the daily variability factor. The 2-parameter lognormal distribution is the probability distribution whose natural logarithm has a normal distribution, and is characterized by parameters μ and σ relative to its logarithmic distribution. If $Y_i = \ln X_i$, $i = 1, \ldots, n$, then the estimates of the parameters are $\hat{\mu} = \bar{Y}$ (sample mean of the natural logarithms), and

$$\hat{\sigma}^2 = \left[\sum_{i=1}^{n} (y_i - \bar{y})^2/(n-1)\right].$$

The daily variability factor is then calculated as

$$VF = \frac{\hat{P}_{99}}{\hat{E}(X)} = \frac{e^{\hat{\mu}+Z\hat{\sigma}}}{(e^{\hat{\mu}})\ \psi_n(.5\hat{\sigma}^2)}$$

where $Z = 2.326$, the standard normal 99th percentile and

$$\psi_n(t) = 1 + \left(\frac{n-1}{n}\right)t + \frac{(n-1)^3}{n^2(n+1)}\ \frac{t^2}{2!} + \ldots$$

is used to determine a minimum variance unbiased estimate of E(X).

Thirty-Day Average Variability Factors

A 30-day average variability factor (VF_{30}) is defined as the ratio of the estimated 99th percentile of the distribution of 30-day averages of daily pollutant values to the estimated long-term mean value. A 30-day average is the arithmetic mean of 30 daily measurements; the sets of measurements used in determining each monthly average are assumed to be distinct. The long-term mean is the long-term arithmetic mean of 30-day averages and is the same as the long-term mean estimated from the daily pollutant values.

EPA developed the 30-day average variability factors on the basis of a statistical result known as the Central Limit Theorem (CLT). The theorem states that, under general and nonrestrictive assumptions, the distribution of a sum of a number of random variables, say n, is approximated by the normal distribution. The approximation improves as the number of terms in the sum increases. The CLT is quite general in that no particular distributional form is assumed for the distribution of the individual values. Thus, this approach is also nonparametric. In most applications (as in determining 30-day variability factors), the theorem is used to approximate the distribution of the average of n observations of a random variable. The result is important because it makes it possible to compute approximate probability statements about the average in a wide range of cases. For instance, it is possible to compute a value below which a specified percentage (e.g., 95 or 99 percent) of the averages on n observations are likely to fall. Most textbooks state that 25 or 30 observations are sufficient for the approximation to be valid although, in many cases, 10 or 15 are adequate. In applying the theorem to the determination of 30-day limitations, one approximates the distribution of the average of 30 observations drawn from the distribution of daily measurements.

Various forms of this theorem exist and are applicable for different situations. A key assumption in the most familiar version of the Central Limit Theorem is that the individual measurements are independent. That is, it is assumed that measurements made on successive days, or any fixed number of days apart, are statistically independent or not related. This assumption of independence is rarely satisfied in an absolute sense in effluent data. In many cases, however, the assumption is satisfied to a degree sufficient to yield a suitable result. Because many of the facilities used to determine variability factors were known to have substantial retention periods, such effluent data can be expected to exhibit some evidence of dependency in the daily data. The Central Limit Theorem can still be used to develop 30-day average variability factors in the case of dependent data. However, some of the necessary calculations must be modified to account for the dependency, and more samples (i.e., larger n) may be required for the approximation to be adequate. In the case of positive dependence (the usual situation with effluent data), the modification will result in a larger estimate of the variance of the mean of 30 observations than would be obtained if independence is assumed. This in turn results in a larger 30-day average variability factor than would be obtained if independence is assumed.

The technical details of adjusting the variance for the case of data dependency are presented below. As stated above, the Central Limit Theorem will still hold for dependent observations with the modification that the variance must be adjusted to reflect the dependence among individual daily mearurements. The covariance between daily measurements is one way to express this dependence; the most straightforward approach to effect the necessary modification is to estimate the variance directly including all the appropriate covariance terms. The variance estimate is based on the following: Let $X_1, X_2, \ldots, X_n$ denote n random variables each with mean μ and variance σ^2. In the case of the effluent data, the X_i, i = 1, ..., n, represent n daily measurements on a particular pollutant and are assumed to have the same mean and variance. The covariance between X_i and X_j is $(\rho)(\sigma^2)$ where $k = |i - j|$, $i \neq j$ and ρ_k is the correlation between measurements k units apart. Correlation is another measure of dependence and is related to covariance. Regardless of the distribution of the X_i, the mean and variance of the average $\bar{X}_n = \sum_{i=1}^{n} X_i/n$ are:

$$\text{mean}(\bar{X}_n) = \mu \quad \text{and}$$

$$\text{var}(\bar{X}_n) = \frac{\sigma^2}{n^2}\left[n + 2\sum_{k=1}^{n-1}(n-k)\,\rho_k\right].$$

In the case that X_i and X_j are independent, the correlation and covariance between them are zero. Therefore, $\text{var}(\bar{X}_n) = \frac{\sigma^2}{n^2}[n + 0] = \frac{\sigma^2}{n}$ which is the well known expression for the variance of a mean of n independent observations.

Given a set of N measurements on the variable X, denoted by $X_1, X_2, \ldots, X_N$, the mean and variance of the average of n dependent observations of X, denoted by X_n, are estimated by

$$\hat{\mu} = \sum_{i=1}^{N} X_i/N$$

and

$$\text{Var}(\hat{\bar{X}}_n) = \frac{s^2}{n^2}\left[n + 2\sum_{k=1}^{n-1}(n-k)r_k\right]$$

respectively, where

$$s^2 = \sum_{i=1}^{N}\frac{(X_i - \hat{\mu})^2}{N-1}$$

and

r_k = estimate of ρ_k, the correlation between measurements that are k units apart ($k < n$)

$$= \sum_{j=1}^{N-k}\frac{(X_j - \hat{\mu})(X_{j+k} - \hat{\mu})/(N-k)}{\sum_{i=1}^{N}(X_i - \hat{\mu})^2/(N-1)}*$$

In order to estimate the variance of $\bar{X}_n$, there must be a sufficient number of measurements to estimate the n - 1 correlations. In the case of an average of 30 observations, there are 29 (lag) correlations that must be estimated. Thirty-day variability factors (incorporating dependence) were estimated for a plant/pollutant data set only if two or more pairs were available to estimate each of the necessary 29 correlations. If sufficient data were not available to estimate these correlations, then the Central Limit Theorem was utilized assuming independence. Thus, the 30-day variability factor was calculated as $VF30 = \frac{\hat{\mu} + Z\,V(\bar{X}_{30})^{1/2}}{\hat{\mu}}$, where $V(X_{30})$ was estimated as described above, with Z = 2.326, the standard normal 99th percentile.

DEVELOPMENT OF VARIABILITY FACTORS USED IN DEVELOPMENT OF PROPOSED NSPS

Tables V-5, V-6, and V-7 present estimates of individual variability factors for specific pharmaceutical plants, based on the results obtained from the above described analyses. EPA determined individual variability factors for best performing pharmaceutical plants employing (1) advanced biological treatment and (2) advanced biological treatment plus effluent filtration.

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* See Wilks, S.S., Mathematical Statistics, Wiley & Sons, 1963, p. 552.

TABLE V-5

INDIVIDUAL VARIABILITY FACTORS FOR
SPECIFIC SUBCATEGORY A AND C PHARMACEUTICAL PLANTS EMPLOYING
ADVANCED BIOLOGICAL TREATMENT

Plant	Subcategory	No. of Observations		Variability Factors			
				Daily Maximum		Maximum 30-day Average	
		BOD_5	TSS	BOD_5	TSS	BOD_5	TSS
12022	A, C	392	395	4.90	3.09	2.59	1.94
12026	C	44	53	4.96	3.03	1.41	1.21
12036	A	366	364	4.33	7.98	1.78	1.71
12132	A, C	200	204	5.05	6.98	1.64	2.04
12161	A, C, D*	249	355	3.22	6.97	1.56	2.19
12236	C	105	105	2.69	3.88	1.22	1.32
Weighted Average Variability Factors				4.29	5.82	1.90	1.89

*About 2 percent of the total wastewater discharge flow results from formulation operations.

TABLE V-6

INDIVIDUAL VARIABILITY FACTORS FOR
SPECIFIC SUBCATEGORY B AND D PHARMACEUTICAL PLANTS EMPLOYING
ADVANCED BIOLOGICAL TREATMENT

Plant	Subcategory	No. of Observations		Variability Factors			
				Daily Maximum		Maximum 30-day Average	
		BOD_5	TSS	BOD_5	TSS	BOD_5	TSS
12015	D	46	195	5.09	5.58	1.43	1.71
12117	B, D	39	51	6.37	5.87	1.30	1.34
12459	D	51	47	6.52	5.36	1.30	1.52
Weighted Average Variability Factors				5.99	5.60	1.34	1.62

TABLE V-7

INDIVIDUAL VARIABILITY FACTORS FOR
SPECIFIC PHARMACEUTICAL PLANTS EMPLOYING
ADVANCED BIOLOGICAL TREATMENT AND
EFFLUENT FILTRATION

Plant	Subcategory	No. of Observations		Variability Factors			
				Daily Maximum		Maximum 30-day Average	
		BOD_5	TSS	BOD_5	TSS	BOD_5	TSS
12317	D	52	262	5.19	6.01	1.43	2.70
12161	A, C, D*	191	319	1.73	5.33	1.16	2.09

*About 2 percent of the total wastewater discharge flow results from formulation operations.

Advanced Biological Treatment

Tables V-5 and V-6 present variability factors for plants in the subcategory A and C and subcategory B and D plant groups where advanced biological treatment is employed. EPA computed variability factors for use in developing effluent limits for NSPS Option A by taking weighted averages of the daily maximum and maximum 30-day average variability factors, weighting the individual factors based on the number of daily observations available for each plant. The weighted average variability factors for each plant group are shown on Tables V-5 and V-6.

[NOTE: In the preamble to the proposed NSPS, EPA is requesting additional information on the performance of biological treatment systems in treating pharmaceutical wastes. The Agency intends to use any new data received with comments on the proposed rules to review its analysis of the variability associated with advanced biological treatment systems in treating pharmaceutical industry wastewaters.]

Filtration

Table V-7 presents variability factors for pharmaceutical plants where advanced biological treatment and effluent filtration are employed. As shown, EPA received sufficient data to compute individual variability factors for only two plants, one representative of the subcategory A and C plant group and one representative of the subcategory B and D plant group. EPA determined variability factors for use in developing effluent limits for NSPS Option B for subcategories A and C based on the variability factors characteristic of plant 12161 and for subcategories B and D based on the variability factors characteristic of plant 12317.

[NOTE: In the preamble to the proposed NSPS, EPA is requesting additional information on the performance of effluent filtration in further removing BOD5 and TSS from pharmaceutical effluents. The Agency intends to use any new data submitted with comments on the proposed rules to review its analysis of the removal capability and variability of effluent filtration when used in combination with advanced biological treatment.]

Summary

Table V-8 presents the variability factors used by the Agency in developing effluent limits consistent with NSPS Options A and B, described previously in this section.

TABLE V-8

INDIVIDUAL VARIABILITY FACTORS FOR
SPECIFIC PHARMACEUTICAL PLANTS EMPLOYING
ADVANCED BIOLOGICAL TREATMENT AND
EFFLUENT FILTRATION

	NSPS Option A[1]				NSPS Option B[2]			
	Daily Maximum		Maximum 30-day Avg.		Daily Maximum		Maximum 30-day Avg.	
Subcategory	BOD_5	TSS	BOD_5	TSS	BOD_5	TSS	BOD_5	TSS
A and C	4.29	5.82	1.90	1.89	1.73	5.33	1.16	2.09
B and D	5.99	5.60	1.34	1.62	5.19	6.01	1.43	2.70

[1]Advanced Biological Treatment.

[2]Advanced Biological Treatment Plus Filtration.

SECTION VI

COST, ENERGY, AND NON-WATER QUALITY ASPECTS

INTRODUCTION

Previous sections describe the respective NSPS control options that were considered as the basis for proposed rules. This section summarizes the cost, energy, and other non-water quality impacts (including implementation requirements, air pollution, noise pollution, and solid waste) of the various treatment options as required by Section 306(b) of the Clean Water Act.

METHODOLOGY FOR DEVELOPMENT OF COSTS

Introduction

This section describes how estimates of the costs of implementation of the various technology options were developed. The actual cost of implementing these technology options can vary at each individual facility, depending on the design and operation of the production facilities and on local conditions. EPA developed treatment costs that are representative of costs anticipated to be incurred at new source direct discharging plants in the pharmaceutical industry. The methodology for development of costs is summarized below.

Model Plant Approach

EPA estimated the costs of implementation of two NSPS technology options in order to determine the economic impact that would result from application of each technology option at new source direct discharging pharmaceutical plants. EPA based its cost estimates on the model plant raw waste characteristics presented in Section IV. EPA selected model plant sizes that are representative of the anticipated sizes of new plants in the pharmaceutical industry. For the subcategory A and C plant group, EPA developed costs for three process flow rates: a large-sized plant discharging 1.2 MGD, a medium-sized plant discharging 0.5 MGD, and a small-sized plant discharging 0.1 MGD. For the subcategory B and D plant group, EPA developed costs for a medium-sized plant discharging 0.05 MGD.

Cost Estimating Criteria

In order to develop cost estimates for the technology options under consideration as the basis for proposed NSPS controlling conventional pollutants, criteria were developed relating to capital, operating, and energy costs. These criteria are presented in Table VI-1. EPA's estimates are pre-engineering cost estimates and are expected to have a variability consistent with this type of estimate, on the order of plus or minus 30 percent.

TABLE VI-1

COST ESTIMATING CRITERIA

1. Capital costs are as of 1982: ENR = 3825

2. Miscellaneous Construction Costs:

Piping:	20% of installed equipment cost[1]
Electrical:	14% of installed equipment cost[1]
Instrumentation:	8% of installed equipment cost[1]
Site Preparation:	6% of installed equipment cost[1]

3. Engineering and Contingencies are 30% of total installed costs, including installed equipment, piping, electrical, instrumentation, and site preparation costs.

4. Annual fixed costs are 22% of capital expenditures.

5. Operation/Maintenance Costs:

Labor:	$24,000/man-year including taxes and fringe benefits[2]
Maintenance:	3% of total capital costs[3]
Sludge Disposal:	$8.64/cubic yard (non-hazardous)[4]
Electricity:	$0.046/kilowatt-hour[5]
Chemicals:	
hydrated lime:	$51/ton[6]
sulfuric acid (66°):	$85/ton[6]
anhydrous ammonia:	$392/ton[4]
phosphoric acid (80%):	$618/ton[4]
chlorine gas:	$441/ton[6]
polymer:	$2.54/lb[6]

1. Development Document for Interim Final Effluent Limitations Guidelines and Proposed New Source Performance Standards for the Pharmaceutical Manufacturing Point Source Category, U.S. EPA, Washington, D.C., December 1976. (6)
2. "National Survey of Professional, Administrative, Technical, and Clerical Pay, March 1981," U.S. Department of Labor, September 1981. (7)
3. Proposed Development Document for Effluent Limitations Guidelines and Standards for the Pharmaceutical Point Source Category, U.S. EPA, Washington, D.C., November 1982. (2)
4. Vendor and Supplier Quotations to Environmental Science and Engineering, Inc., Gainesville, Florida, 1982 and 1983. (8)
5. "Electric Utility Company Monthly Statement," March 1980 - Forward: Federal Energy Regulatory Commission, Form 5, as cited in Monthly Energy Review, U. S. Department of Energy, Energy Information Administration, DOE/EIA-0035 (81/12), December 1981. (9)
6. Innovative and Alternative Technology Assessment Manual, U.S. EPA, Office of Water Program Operations, Washington, D. C., February 1980. (10)

All costs presented are in terms of 1982 dollars. Since construction costs escalate, these estimates may be adjusted through the use of appropriate cost indices. The most accepted and widely-used cost index in the engineering field is the Engineering News Record (ENR) construction cost index. The ENR Index for cost data presented in this document is 3,825.

Costs for Implementation of NSPS Options

EPA estimated the costs associated with baseline conditions (i.e., a new source must comply with BPT conventional pollutant limits) and with two technology options capable of controlling conventional pollutant discharges from new direct discharging plants in the subcategory A and C and the subcategory B and D plant groups of the pharmaceutical industry. To develop the cost estimates, the Agency primarily relied on information contained in Section VIII of the Development Document for Interim Final Effluent Limitations Guidelines and Proposed New Source Performance Standards for the Pharmaceutical Manufacturing Point Source Category (U.S. EPA, December 1976)(6) and on information contained in Supplement A of the BPT rulemaking record.

EPA first estimated total capital costs using the methodology described in the 1976 Development Document and Supplement A. These costs were in terms of May 1976 dollars. Next, the Agency updated these costs, first to September 1980 dollars and then to 1982 dollars using the ENR index. These estimates were then adjusted to reflect solids dewatering based on the application of horizontal belt filters rather than vacuum filters. Horizontal belt filter costs were derived from information contained in Innovative and Alternative Technology Assessment Manual, EPA-430/9-78-009, U.S. EPA, Office of Water Programs Operations, Washington, D.C., February 1980. (10) EPA updated unit costs of chemicals, labor, energy, and sludge disposal to September 1980 dollars and then adjusted the unit costs to 1982 dollars using the ENR index. The Agency used these unit costs (shown in Table VI-1) to estimate operating and maintenance costs associated with compliance with baseline conditions and with two technology options capable of further reducing conventional pollutant discharges from new source direct discharging pharmaceutical plants.

Baseline: In the absence of nationally applicable NSPS, new source direct discharging pharmaceutical plants must, at a minimum, attain BPT limits for BOD5 and TSS. Therefore, BPT is the baseline condition. Design criteria for the baseline end-of-pipe biological treatment systems for the subcategory A and C and the subcategory B and D plant groups are presented in Table VI-2.

NSPS Option A. Base NSPS for BOD5 and TSS on the performance of the best plants with advanced biological treatment. Design criteria for the end-of-pipe biological treatment systems for the subcategory A and C and the subcategory B and D plant groups are presented in Table VI-3.

TABLE VI-2

DESIGN BASIS OF THE TREATMENT SYSTEMS
EXPECTED TO BE EMPLOYED AT NEW SOURCE
PHARMACEUTICAL INDUSTRY DIRECT DISCHARGERS
TO MEET BASELINE EFFLUENT LEVELS

Wastewater Pumping:

Design flow: Average daily flow
Basis for power cost: 15 m. total dynamic head

Flow Equalization (Subcategory B-D only):

Detention time: 48 hrs; concrete basins for volumes less than 52 cu. m., earthen basins for volumes greater than 52 cu. m.

Aeration design requirement: 0.77 hp per cu. m.

Diversion Basin (Subcategory A-C only):

Detention time: 48 hrs

Neutralization (Subcategory A-C only):

Detention time: 20 min
Chemical dosage: lime = 4.3 kg/cu. m., acid = 15.3 kg/cu. m.

Flocculator - Clarifiers:

Type: Primary, secondary, and final for subcategory A-C; secondary for subcategory B-D
Overflow rate: 24 cu. m./d/sq. m.
Sidewater depth: 2.1 to 4.0 m.

Activated Sludge Basin:

Number of basins: 2 minimum
Hydraulic detention time: 4 days for subcategory A-C;
1.06 days for subcategory B-D

Nutrient feed: BOD applied:N:P = 100:5:1
Aeration design requirements: 1 kg O_2/kg BOD_5 removed
16 kg O_2/aerator h.p./d

Sludge Thickener (Subcategory A-C only):

Sludge loading rate: 29.3 kg/sq. m./day

TABLE VI-2
(continued)

DESIGN BASIS OF THE TREATMENT SYSTEMS
EXPECTED TO BE EMPLOYED AT NEW SOURCE
PHARMACEUTICAL INDUSTRY DIRECT DISCHARGERS
TO MEET BASELINE EFFLUENT LEVELS

Aerobic Digester:

Detention time: 20 days
Aerator design requirements: 1.6 kg O_2/kg VSS destroyed
0.044 h.p./cu. m.

Solids Dewatering:

Type: Horizontal belt-filter press
Loading rate: 7.1 kg/sq. m./d
Chemical dosage: 3 kg of polymer/kkg of solids

Trickling Filter (Subcategory A-C only):

Loading rate: 0.5 cu. m./sq. m./d
Depth: 3.7 m.

Polishing Ponds (Subcategory A-C only):

Detention time: 2 days
Solids removal: Pumping from multiple bottom draw-offs

Effluent Chlorination:

Detention time: 30 min.
Chemical dosage: 0.1 kg/cu. m.

Primary/Biological Sludge Transportation and Disposal:

Hauling distance: 64 km
Sludge content: Primary and biological digested sludge at 100 kg/cu. m.
Sludge disposal: Sanitary landfill, off-site

NOTE: Subcategory A-C model treatment system based on subcategory C model system in 1976 development document. (6)

Subcategory B-D model treatment system based on subcategory D model system in 1976 development document. (6)

TABLE VI-3

DESIGN BASIS OF THE TREATMENT SYSTEMS
EXPECTED TO BE EMPLOYED TO MEET
NSPS OPTION A EFFLUENT LEVELS

Wastewater Pumping:

Design flow: Average daily flow
Basis for power cost: 15 m. total dynamic head

Flow Equalization (Subcategory B-D only):

Detention time: 48 hrs; concrete basins for volumes less than 52 cu. m., earthen basins for volumes greater than 52 cu. m.

Aeration design requirement: 0.77 hp per cu. m.

Diversion Basin (Subcategory A-C only):

Detention time: 48 hrs

Neutralization (Subcategory A-C only):

Detention time: 20 min
Chemical dosage: lime = 4.3 kg/cu. m., acid = 15.3 kg/cu. m.

Flocculator - Clarifiers:

Type: Primary, secondary, and final for subcategory A-C; secondary for subcategory B-D
Overflow rate: 24 cu. m./d/sq. m.
Sidewater depth: 2.1 to 4.0 m.

Activated Sludge Basin:

Number of basins: 2 minimum
Hydraulic detention time: 5 days for subcategory A-C;
1.33 days for subcategory B-D

Nutrient feed: BOD applied:N:P = 100:5:1
Aeration design requirements: 1 kg O_2/kg BOD_5 removed
16 kg O_2/aerator h.p./d

Sludge Thickener (Subcategory A-C only):

Sludge loading rate: 29.3 kg/sq. m./day

TABLE VI-3

DESIGN BASIS OF THE TREATMENT SYSTEMS
EXPECTED TO BE EMPLOYED TO MEET
NSPS OPTION A EFFLUENT LEVELS
(continued)

Aerobic Digester:

Detention time: 20 days
Aerator design requirements: 1.6 kg O_2/kg VSS destroyed
0.044 h.p./cu. m.

Solids Dewatering:

Type: Horizontal belt-filter press
Loading Rate: 7.1 kg/sq. m./d
Chemical dosage: 3 kg of polymer/kkg of solids

Trickling Filter (Subcategory A-C only):

Loading rate: 0.5 cu. m./sq. m./d
Depth: 3.7 m.

Polishing Ponds (Subcategory A-C only):

Detention time: 2 days
Solids removal: Pumping from multiple bottom draw-offs

Effluent Chlorination:

Detention time: 30 min
Chemical dosage: 0.1 kg/cu. m.

Primary/Biological Sludge Transportation and Disposal:

Haul distance: 64 km
Sludge content: Primary and biological digested sludge at
100 kg/cu. m.
Sludge Disposal: Samitary landfill, off-site

NOTE: Subcategory A-C model treatment system based on subcategory C model system in 1976 development document. (6)

Subcategory B-D model treatment system based on subcategory D model system in 1976 development document. (6)

NSPS Option B. Base NSPS for BOD5 and TSS on the performance of the best plants employing advanced biological treatment and effluent filtration (i.e., Option A plus effluent filtration). Design criteria for the biological treatment systems are the same as for NSPS Option A. Design criteria for the end-of-pipe filtration systems are shown in Table VI-4.

Table VI-5 presents capital, operating and maintenance, and total annual costs of implementation of baseline treatment and implementation of NSPS Options A and B at model new source pharmaceutical plants. Table VI-6 presents a summary of detailed cost estimates for each component of the treatment systems expected to be used at a new source subcategory A or C plant to comply with baseline conditions or with NSPS Options A or B.

ENERGY AND NON-WATER QUALITY IMPACTS

Energy Requirements

The implementation of the control and treatment options considered as the basis of these proposed rules are expected to affect energy demand at new source pharmaceutical plants. Table VI-7 summarizes Agency estimates of total energy used at new source direct discharging plants for the baseline case and after the application of each specific NSPS option. Total energy is presented in terms of equivalent barrels of No. 6 fuel oil; purchased electrical energy (kwh) required was converted to heat energy (BTU) at a conversion of 10,500 BTU/kwh, which reflects the average efficiency of electrical power generation. To allow a comparison with overall pharmaceutical industry energy use, EPA estimated the average total energy consumed by the pharmaceutical industry based on information in the 1980 Annual Survey of Manufactures, Fuels and Electric Energy Consumed, Industry Groups and Industries, M80(AS)-4.1, U.S. Department of Commerce, Bureau of the Census. (11) This estimate includes purchased fuels and electrical energy, distillate and residual fuel oil, and energy generated less that sold. Based on the survey information, the total energy consumed by the pharmaceutical industry is equivalent to about 28.8 billion kilowatt-hours. This is equivalent to about 51.5 million barrels of No. 6 fuel oil.

Solid Waste Generation

The implementation of the control and treatment options considered as the basis of proposed rules is expected to result in increased generation of wastewater treatment sludges. Wastewater treatment facilities produce both primary and biological sludges that are usually dewatered prior to disposal. The amount of wastewater treatment sludge generated depends on a number of conditions including: 1) raw waste characteristics; 2) the existence, efficiency, and/or type of primary treatment; 3) the type of biological treatment system employed; and 4) the existence, efficiency, and/or type of secondary clarification.

TABLE VI-4

DESIGN BASIS OF THE FILTRATION SYSTEM
EXPECTED TO BE EMPLOYED TO MEET
NSPS OPTION B EFFLUENT LEVELS

Filtration:	
Type:	Multimedia
Hydraulic Loading:	0.122 cu. m./min/sq. m.
Backwash Rate:	0.813 cu. m./min/sq. m. for 10 minutes

TABLE VI-5

MODEL PLANT COSTS ASSOCIATED WITH
MEETING BASELINE, NSPS OPTION A, AND NSPS
OPTION B BOD_5 AND TSS FINAL EFFLUENT CONCENTRATIONS

Subcategory	Costs (Millions of 1982 Dollars) Capital	O & M	Total Annual
Subcategory A and C			
1.2 MGD			
Baseline	12.846	1.496	4.322
NSPS Option A	14.115	1.572	4.678
NSPS Option B	15.147	1.624	4.957
0.5 MGD			
Baseline	7.678	0.651	2.340
NSPS Option A	8.036	0.741	2.507
NSPS Option B	8.806	0.773	2.711
0.1 MGD			
Baseline	3.387	0.244	0.989
NSPS Option A	3.480	0.254	1.020
NSPS Option B	3.797	0.266	1.102
Subcategory B and D			
0.05 MGD			
Baseline	2.026	0.121	0.567
NSPS Option A	2.069	0.123	0.579
NSPS Option B	2.297	0.132	0.637

TABLE VI-6

SUMMARY OF COSTS FOR TREATMENT
SYSTEM COMPONENTS FOR THE 1.2 MGD
SUBCATEGORY A AND C MODEL NEW SOURCE PLANT

Treatment Component	COST ESTIMATES ($1000) Baseline	NSPS Option A	NSPS Option B
CAPITAL			
1) Low lift pump station	125	125	125
2) Neutralization tanks	44	44	44
3) Primary Floc-Clarifier	350	350	350
4) Secondary Floc-Clarifier	350	350	350
5) Final Floc-Clarifier	350	350	350
6) Aeration Basin	550	670	670
7) Sludge Thickener	98	117	118
8) Digester	290	340	350
9) Digester Aerators	212	340	294
10) Aeration Basin Aerators	468	539	520
11) Belt Press	72	78	79
12) Trickling Filter	467	467	467
13) Diversion Basin	47	47	47
14) Polishing Pond	49	49	49
15) Polymer Feed	22	24	24
16) Chlorination Facilities	65	65	65
17) Lime Feed	151	151	151
18) H_2SO_4 Feed	35	35	35
19) Primary Sludge Pumps	16	21	21
20) Sludge Transfer	12	13	13
21) Nutrient Addition	79	79	79
22) Recycle Pumps	13	13	13
23) Control Building	177	177	177
24) Flow Measurement	25	25	25
25) Multimedia Filter	NA	NA	380
Subtotal	4,067	4,469	4,796
Misc. Construction	1,952	2,145	2,302
Engr. & Contingencies	1,806	1,984	2,129
Total (May 1976 Dollars)	7,825	8,598	9,227
Total (1982 Dollars)	12,846	14,115	15,147

TABLE VI-6
(Continued)

Component	Baseline	COST ESTIMATES ($1000) NSPS Option A	NSPS Option B
TOTAL ANNUAL			
Energy	319	340	341
Labor	146	146	146
Maintenance (@ 0.03)	334	367	394
Sludge Hauling	169	177	188
Chemicals	330	334	340
Capital Recovery (@ 22%)	2,452	2,695	2,892
Total (September 1980 Dollars)	3,750	4,059	4,301
Total (1982 Dollars)	4,322	4,678	4,957

TABLE VI-7

ENERGY USE AT NEW SOURCE PHARMACEUTICAL PLANTS TO ATTAIN NSPS OPTION A AND NSPS OPTION B EFFLUENT LEVELS

Subcategory	Flow (MGD)	Energy Requirements for Wastewater Treatment (bbl of oil/yr)	Energy Increase Over Baseline Wastewater Treatment Energy Requirements
Subcategory A and C	1.2		
Baseline		13,314	-
NSPS Option A		14,190	6.6 %
NSPS Option B		14,232	6.9 %
Subcategory B and D	0.05		
Baseline		313	-
NSPS Option A		351	12.1 %
NSPS Option B		380	21.4 %

Table VI-8 summarizes Agency estimates of wastewater sludge generation for the baseline case and after the application of each NSPS technology option.

Air Pollution and Noise Potential

The technologies under consideration are not a significant source of noise potential or air pollution. EPA anticipates that implementation of the control and treatment options under consideration will have no direct impact on air pollution or noise pollution.

TABLE VI-8

SOLID WASTE GENERATION AT NEW SOURCE
PHARMACEUTICAL PLANTS TO ATTAIN NSPS OPTION A
AND NSPS OPTION B EFFLUENT LEVELS

Subcategory	Flow (MGD)	Wastewater Sludge Generation (million lbs/yr)	Sludge Increase Over Baseline Wastewater Sludge Generation
Subcategory A and C	1.2		
Baseline		5.140	-
NSPS Option A		5.337	3.8
NSPS Option B		5.343	3.9
Subcategory B and D	0.05		
Baseline		0.069	-
NSPS Option A		0.071	2.8
NSPS Option B		0.071	2.8

SECTION VII

EFFLUENT REDUCTION ATTAINABLE THROUGH THE APPLICATION OF NEW SOURCE PERFORMANCE STANDARDS

GENERAL

The basis for new source performance standards (NSPS) under Section 306 of the Act is the best available demonstrated technology. At new plants, the opportunity exists to design the best and most efficient production processes and wastewater treatment facilities. Therefore, Congress directed EPA to consider the best demonstrated process changes, in-plant controls, and end-of-pipe treatment technologies that reduce pollution to the maximum extent feasible. As a result, limitations for NSPS should represent the most stringent numerical values attainable through the application of demonstrated control technology for all pollutants (conventional, nonconventional, and toxic).

IDENTIFICATION OF THE TECHNOLOGY BASIS OF PROPOSED NSPS

The technology basis selected for control of BOD5 and TSS under proposed NSPS is advanced biological treatment (i.e., biological treatment with longer detention time than that considered as the basis of effluent limitations reflecting the best practicable control technology currently available (BPT)) in combination with effluent filtration.

PROPOSED NSPS

Table VII-1 presents proposed NSPS for the conventional pollutants BOD5 and TSS at pharmaceutical manufacturing facilities.

RATIONALE FOR THE SELECTION OF THE TECHNOLOGY BASIS OF PROPOSED NSPS

As discussed in Section V, EPA identified two options that could form the basis of NSPS controlling the discharge of conventional pollutants from pharmaceutical manufacturing facilities. EPA based proposed NSPS on the application of biological treatment and effluent filtration because filtration is an available, demonstrated technology in this industry that results in additional conventional pollutant removal beyond that attained by the application of advanced biological treatment only.

METHODOLOGY USED FOR DEVELOPMENT OF PROPOSED NSPS

For subcategories B and D, EPA determined attainable long-term average BOD5 and TSS effluent concentrations resulting from the application of advanced biological treatment and effluent filtration by analyzing effluent data from three subcategory B and D plants employing this combination of end-of-pipe treatment technologies.

TABLE VII-1

PROPOSED CONVENTIONAL POLLUTANT NSPS
FOR THE
PHARMACEUTICAL MANUFACTURING POINT SOURCE CATEGORY

	Pollutant			
	BOD_5		TSS	
Subcategory	Maximum 30-Day Average	Daily Maximum	Maximum 30-Day Average	Daily Maximum
A-Fermentation	76.8 mg/l	115.0 mg/l	193.0 mg/l	491.0 mg/l
B-Extraction	11.2 mg/l	40.7 mg/l	26.5 mg/l	58.9 mg/l
C-Chemical Synthesis	76.8 mg/l	115.0 mg/l	193.0 mg/l	491.0 mg/l
D-Mixing/Compounding and Formulation	11.2 mg/l	40.7 mg/l	26.5 mg/l	58.9 mg/l

For subcategories A and C, EPA identified six plants where advanced biological treatment is employed. The Agency analyzed effluent data for these six plants and determined attainable long-term average BOD5 and TSS effluent concentrations resulting from the application of advanced biological treatment. EPA also determined the BOD5 and TSS removal capability of effluent filtration based on available data from the one subcategory A/C plant employing the combination of advanced biological treatment and effluent filtration. This plant has relatively low raw waste concentrations compared to other fermentation and chemical synthesis plants. Rather than propose NSPS based on data for this one plant, EPA computed long-term average BOD5 and TSS effluent concentrations by reducing the attainable long-term average BOD5 and TSS effluent concentrations for advanced biological treatment by the percentage removals of BOD5 and TSS that occur at the one plant employing both advanced biological treatment and effluent filtration.

For all four subcategories, EPA calculated maximum 30-day average and daily maximum limitations by multiplying attainable long-term average BOD5 and TSS effluent concentrations by appropriate variability factors, as discussed in Section V of this document.

COST OF APPLICATION AND EFFLUENT REDUCTION BENEFITS

EPA estimates that a model new source subcategory A or C plant discharging 1.2 million gallons of wastewater per day (MGD), in complying with proposed NSPS, would remove 1.63 million pounds per year of BOD5 and TSS beyond that removed in complying with BPT effluent limitations. The incremental capital and total annual costs beyond BPT would be $2.30 and $0.64 million, respectively (1982 dollars). EPA estimates that a model new source subcategory B or D plant discharging 0.050 MGD of wastewater, in complying with NSPS, would remove about 17,000 pounds per year of BOD5 and TSS beyond BPT. The incremental capital and total annual costs beyond BPT would be $271,000 and $70,000, respectively (1982 dollars).

NON-WATER QUALITY ENVIRONMENTAL IMPACTS

Sections 304(b) and 306 of the Act require EPA to consider the non-water quality environmental impacts (including energy requirements) of certain regulations. In conformance with these provisions, EPA considered the effect of these regulations on air pollution, solid waste generation, and energy consumption, as summarized below.

Implementation of proposed NSPS would not substantially increase air pollution, energy use, or solid waste generation. The proposed regulations are not expected to cause any significant air pollution problems. EPA estimates that compliance with proposed NSPS for conventional pollutants will increase energy use by less than one percent at subcategory A or C and subcategory B or D plants.

EPA estimates that, to comply with proposed NSPS, the incremental solid waste generated at a model new source fermentation (subcategory A) or chemical synthesis (subcategory C) plant discharging 1.2 MGD of

wastewater and a model extraction (subcategory B) or formulation (subcategory D) plant discharging 0.050 MGD of wastewater will be approximately 200,000 and 2,100 additional pounds per year of wastewater treatment sludge, respectively, beyond that generated in meeting BPT effluent limitations. This is equal to an incremental increase of about 3.9 percent for subcategory A or C plants and about 3.0 percent for subcategory B or D plants over that generated to meet BPT effluent limitations. The solid wastes generated through wastewater treatment at pharmaceutical plants have not been listed as hazardous in regulations promulgated by the Agency under Subtitle C of the Resource Conservation and Recovery Act (RCRA) (see 45 FR 33066; May 19, 1980). Accordingly, it does not appear likely that the wastewater sludges generated by new source pharmaceutical plants under the proposed NSPS will be subject to the comprehensive RCRA program establishing requirements for persons handling, transporting, treating, storing, and disposing of hazardous wastes. The Agency's estimates of the costs of this regulation include the cost of handling these sludges as a non-hazardous waste.

SECTION VIII

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SECTION IX

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