ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 439

[WH-FRL 2443-2]

Pharmaceutical Manufacturing Point Source Category Effluent Limitations Guidelines, Pretreatment Standards, and New Source Performance Standards

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final regulation.

SUMMARY: This regulation establishes effluent limitations guidelines and standards limiting the discharge of pollutants into navigable waters by existing and new sources that conduct pharmaceutical manufacturing operations. These regulations are issued under the Clean Water Act and the Settlement Agreement in *Natural Resources Defense Council, Inc.* v. *Train,* 8 ERC 2120 (D.D.C. 1976), *modified,* 12 ERC 1833 (D.C.C. 1979), modified by Orders dated October 26, 1982, and August 2, 1983.

The purpose of this regulation is to specify for certain pollutants "best practicable control technology currently available" (BPT) effluent limitations guidelines, "best available technology economically achievable" (BAT) effluent limitations guidelines, "new source performance standards" (NSPS), and pretreatment standards for existing and new sources (PSES and PSNS, respectively) for the pharmaceutical manufacturing industry.

DATES: In accordance with 40 CFR 100.01 (45 FR 26048), this regulation shall be considered issued for purposes of judicial review at 1:00 p.m. Eastern time on November 10, 1983. This regulation shall become effective December 12, 1983, except for provisions in the following sections which allow facilities not using or generating cyanide to certify to that effect instead of monitoring for cyanide. These certification provisions are contained in the following sections: §§ 439.14–439.17, 439.24–439.27, 439.34–439.37, and 439.44–439.47. These certification provisions have been submitted to the Office Management and Budget (OMB) and are not effective until OMB has approved them under the Paperwork Reduction Act.

The compliance date for the BAT regulations is as soon as possible, but in any event, no later then July 1, 1984. The compliance date for new source performance standards (NSPS) and pretreatment standards for new sources (PSNS) is the date the new source begins operations. The compliance date for pretreatment standards for existing sources (PSES) is October 27, 1986.

Under Section 509(b)(1) of the Clean Water Act, judicial review of this regulation can be made only by filing a petition for review in the United States Court of Appeals within 90 days after the regulation is considered issued for purposes of judicial review. Under Section 509(b)(2) of the Clean Water Act, the requirements in this regulation may not be challenged later in civil or criminal proceedings brought by EPA to enforce these requirements.

ADDRESSES: The basis for this regulation is detailed in four major documents. See **SUPPLEMENTARY INFORMATION** (under "XIV. Availability of Technical Information") for a description of each document. Copies of the technical and economic documents may be obtained from the National Technical Information Service, Springfield, Virginia 22161 (Phone: (703) 487–4600). For additional technical information, contact Dr. Frank H. Hund, Effluent Guidelines Division (WH–552), U.S. Environmental Protection Agency, 401 M Street, SW., Washington, D.C. 20460 (Phone (202) 382–7182). For additional economic information, contact Mr. Joseph Yance, Office of Analysis and Evaluation (WH–586), U.S. Environmental Protection Agency, 401 M Street, SW., Washington, D.C. 20460 (Phone (202) 382–5379).

On January 3, 1984, the complete public record for this rulemaking including the Agency's responses to comments on the proposed regulation, will be available for review in EPA's Public Reference Unit, Room 2404 (Rear) (EPA Library), 401 M Street, SW., Washington, D.C. The EPA public information regulation (40 CFR Part 2) provides that a reasonable fee may be charged for copying.

FOR FURTHER INFORMATION CONTACT: Dr. Frank Hund at the address listed above or by calling (202) 382–7182.

SUPPLEMENTARY INFORMATION:

Organization of this Notice

I. Legal authority
II. Scope of this rulemaking and prior regulations
III. Summary of legal background
IV. Summary of methodology and data gathering efforts
V. Summary of promulgated regulations and changes from proposal
VI. Costs, economic impacts, Executive Order 12291, Regulatory Flexibility Analysis, and Small Business Administration (SBA) loans
VII. Pollutants and subcategories not regulated
VIII. Non-water quality environmental impacts
IX. Best management practices
X. Upset and bypass provisions
XI. Variances and modifications
XII. Implentation of limitations and standar
XIII. Public participation—responses to maj comments
XIV. Availability of technical information
XV. Office of Management and Budget (OM review
XVI. List of subjects in 40 CFR Part 439

Appendices

A. Abbreviations, Acronyms and Other Terms Used in this Notice
B. Toxic Pollutants Not Detected in the Treated Effluents of Direct Dischargers
C. Toxic Pollutants Detected in Treated Effluents of Direct Dischargers: (1) Fron a Small Number of Sources, (2) Detecte in Only Trace Amounts or (3) Sufficien Controlled by Existing Technologies
D. Toxic Pollutants Not Detected in the Effluent of Indirect Dischargers
E. Toxic Pollutants Detected in the Effluent Indirect Dischargers Whose Toxicity ai Amount (Taken Together) Is So Insignificant as Not To Justify Developing Pretreatment Regulations

I. Legal Authority

This regulation is being promulgated under the authority of Sections 301, 30 306, 307, 308, and 501 of the Clean Wat Act (the Federal Water Pollution Cont Act Amendments of 1972, 33 U.S.C. 12 *et seq.,* as amended by the Clean Wat Act of 1977, Pub. L. 95–217), also calle "the Act." It is also being promulgated in response to the Settlement Agreeme 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.

II. Scope of This Rulemaking and Prio Regulations

A. Prior Regulations

EPA promulgated interim final BPT regulations for the pharmaceutical manufacturing point source category o November 17, 1976 (41 FR 50676; 40 CF Part 439, Subparts A–E). The five subcategories of the pharmaceutical industry (40 CFR Part 439) are:

- Subpart A—Fermentation Products Subcategory
- Subpart B—Extraction Products Subcategory
- Subpart C—Chemical Synthesis Products Subcategory
- Subpart D—Mixing/Compounding a Formulation Subcategory
- Subpart E—Research Subcategory

The 1976 BPT regulations set month limitations for five-day biochemical oxygen demand (BOD5) and chemical oxygen demand (COD) based on perc removals for all subcategories. No dai maximum effluent limitations were

established for these two parameters. The pH was set within the range of 6.0 to 9.0 standard units. The regulation also set maximum 30 day average total suspended solids (TSS) limitations for subcategories B, D, and E only. No TSS values were established for subcategories A and C. Subpart A (applicable to the fermentation operations subcategory) was amended (42 FR 6814) on February 4, 1977, to improve the language referring to separable mycelia and solvent recovery. In addition, the amendment allowed the inclusion of spent beers (broths) in the calculation of raw waste loads for Subpart A in those instances where the spent beer is actually treated in the wastewater treatment system. These regulations were never challenged and are presently in effect.

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 Subparts B, D, and E; (b) proposed BPT TSS effluent limitations for Subparts A and C; (c) proposed to modify the existing BPT COD effluent limitations for Subparts A, B, C, D, and E; (d) proposed BPT cyanide effluent limitations for Subparts A, B, C, and D; and (e) proposed BAT and BCT effluent limitations, NSPS, PSES, and PSNS to apply uniformly to subcategories A, B, C, and D. EPA did not propose to establish regulations controlling other toxic pollutant discharges from pharmaceutical research for the reasons discussed in Section VII of this preamble (Pollutants and Subcategories Not Regulated).

With the few exceptions discussed below, the Agency is not modifying the previously promulgated BPT limitations for Subparts A through E. However, in order to publish a complete set of all applicable requirements, the BPT limitations already in effect are reprinted in today's rule. Existing BPT limitations not modified in today's rulemaking are not subject to legal challenge.

B. Scope of this Rulemaking

This final regulation, which was proposed on November 26, 1982 (47 FR 53584), establishes effluent limitations guidelines and standards for existing and new pharmaceutical manufacturing facilities. Pharmaceutical manufacturers use many different methods and raw materials to create a wide range of products. These products include medicinal and feed grades of all organic chemicals having therapeutic value, whether obtained by chemical synthesis, by fermentation, by extraction from naturally occurring plant or animal substances, or by refining a technical grade product.

The pharmaceutical products, processes, and activities covered by this proposal include:

a. Biological products covered by the U.S. Department of Commerce, Bureau of the Census Standard Industrial Classifications (SIC) Code No. 2831.

b. Medicinal chemicals and botanical products covered by SIC Code No. 2833.

c. Pharmaceutical products covered by SIC Code No. 2834.

d. All fermentation, biological, and natural extraction, chemical synthesis, and formulation products which are considered as pharmaceutically active ingredients by the Food and Drug Administration, but are not covered by SIC Code Nos. 2831, 2833, or 2834. (Also, products of these types such as citric acid which are not regarded as pharmaceutical active ingredients will be included if they are manufactured by a pharmaceutically manufacturer by processes, and result in wastewaters, which closely correspond to those of a pharmaceutical product.)

e. Cosmetic preparation covered by SIC Code No. 2844 which function as a skin treatment. (This group of preparations does not include products such as lipsticks or perfumes which serve to enhance appearance or to provide a pleasing odor, but do not provide skin care. In general, this also excludes deodorants, manicure preparations, and shaving preparations which do not primarily function as a skin treatment.)

f. Products with multiple end uses which are attributable to pharmaceutical manufacturing as a final pharmaceutical product, component of a pharmaceutical formulation, or pharmaceutical intermediate. Products which have non-pharmaceutical uses may also be covered entirely by this point source category provided that the product(s) was (were) primarily intended for use as a pharmaceutical.

g. Pharmaceutical research which includes biological, microbiological, and chemical research, product development, clinical and pilot plant activities. (This does not include farms which breed, raise, and/or hold animals for research at another site. This also does not include ordinary feedlot or farm operations utilizing feed which contains pharmaceutically active ingredients.)

A number of products and/or activities such as surgical and medical instruments and medical laboratory activity are not part of the pharmaceutical manufacturing category. A descriptive listing of the products and/or activities which are specifically excluded from the pharmaceutical manufacturing category may be found in Section II of the *Development Document for Effluent Limitations Guidelines, New Source Performance Standards, and Pretreatment Standards for the Pharmaceutical Manufacturing Point Source Category.*

EPA is promulgating BPT and BAT effluent limitations, NSPS, and pretreatment standards for existing and new sources (PSES and PSNS, respectively) for the pharmaceutical manufacturing point source category. Concurrent with this regulation, EPA is proposing NSPS to control the discharge of two conventional pollutants (BOD5 and TSS) from the pharmaceutical plants. As explained below, EPA will not establish BCT limitations for the pharmaceutical industry until promulgation of the general methodology for determining appropriate levels of conventional pollutant control under BCT. We are also postponing a final decision on BAT limitations and NSPS for the nonconventional pollutant COD.

III. Summary of Legal Background

The Federal Water Pollution Control Act Amendments of 1972 established a comprehensive program to "restore and maintain the chemical, physical, and biological integrity of the Nation's waters," Section 101(a). To implement the Act, EPA was to issue effluent limitations guidelines, pretreatment standards, and new source performance standards for industrial dischargers.

The Act included a timetable for issuing these standards. However, EPA was unable to meet many of the deadlines and, as a result, in 1976, it was sued by several environmental groups. In settling this lawsuit, EPA and the plaintiffs executed a "Settlement Agreement" which was approved by the court. This agreement required EPA to develop a program and adhere to a schedule for controlling 65 "priority" pollutants and classes of pollutants. In carrying out this program, EPA must promulgate BAT effluent limitations guidelines, pretreatment standards, and new source performance standards for 21 major industries. See *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 65 toxic pollutants and classes of pollutants potentially include thousands of specific pollutants. EPA selected 129 specific

toxic pollutants for study in this rulemaking and other industry rulemakings. Since initiation of this rulemaking effort, three toxic pollutants have been removed from the list of 129 toxic pollutants: Dichlorodifluoromethane, trichlorofuloromethane, and bis-chloromethyl ether (46 FR 2266 and 46 FR 10723).

Many of the basic elements of the Settlement Agreement were incorporated into the Clean Water Act of 1977. Like the Agreement, the Act stressed control of toxic pollutants, including the 65 "priority" pollutants. In addition, to strengthen the toxic control program, Section 304(e) of the Act authorizes the Administrator to prescribe "best management practices" (BMPs) to prevent the release of toxic and hazardous pollutants from plant site runoff, spillage or leaks, sludge or waste disposal, and drainage from raw material storage associated with, or ancillary to, the manufacturing or treatment process.

Under the Act, the EPA is to set a number of different kinds of effluent limitations. These are discussed in detail in the preamble to the proposed regulation and in the Development Document. They are summarized briefly below:

1. *Best Practicable Control Technology (BPT).* BPT limitations are generally based on the average of the best existing performance by plants of various sizes, ages, and unit processes within the industry or subcategory for control of familiar (i.e., classical) pollutants.

In establishing BPT limitations, we consider the total cost of applying the technology in relation to the effluent reduction derived, the age of equipment and facilities involved, the processes employed, process changes required, engineering aspects of the control technologies, and nonwater quality environmental impacts (including energy requirements). We balance the total cost of applying the technology against the effluent reduction.

2. *Best Available Technology (BAT).* BAT limitations, in general, represent the best existing performance in the industrial subcategory or category. The Act establishes BAT as the principal national means of controlling the direct discharge of toxic and nonconventional pollutants to waters of the United States.

In arriving at BAT, the Agency considers the age of the equipment and facilities involved, the process employed, the engineering aspects of the control technologies, process changes, the cost of achieving such effluent reduction, and nonwater quality environmental impacts. The Agency retains considerable discretion in assigning the weight to be accorded these factors.

3. *Best Conventional Pollutant Control Technology (BCT).* The 1977 Amendments to the Clean Water Act added Section 301(b)(2)(E), establishing "best conventional pollutant control technology" (BCT) for discharge of conventional pollutants from existing industrial point sources. Section 304(a)(4) designated the following as conventional pollutants: BOD, TSS, fecal coliform, pH, and any additional pollutants defined by the Administrator as conventional. The Administrator designated oil and grease as "conventional" on July 30, 1979 (44 FR 4450).

BCT is not an additional limitation but replaces BAT for the control of conventional pollutants. In addition to other factors specified in Section 304(b)(4)(B), the Act requires that BCT limitations be assessed in light of a two part "cost-reasonableness" test. *American Paper Institute* v. *EPA*, 660 F. 2d 954 (4th Cir. 1981). The first test compares the cost for private industry to reduce its conventional pollutants with the costs to publicly owned treatment works for similar levels of reduction in their discharge of these pollutants. The second test examines the cost effectiveness of additional industrial treatment beyond BPT. EPA must find that limitations are "reasonable" under both tests before establishing them as BCT. In no case may BCT be less stringent than BPT.

EPA published its methodology for carrying out the BCT analysis on August 29, 1979 (44 FR 50732). In the case mentioned above, the Court of Appeals ordered EPA to correct data errors underlying EPA's calculation of the first test, and to apply the second cost test. (EPA had argued that a second cost test was not required.)

A revised methodology for the general development of BCT limitations was proposed on October 29, 1982 (47 FR 49176). BCT limits for this industry are accordingly deferred until promulgation of the final methodology for BCT development.

4. *New Source Performance Standards (NSPS).* NSPS are based on the best available demonstrated technology (BDT). New plants have the opportunity to install the best and most efficient production processes and wastewater treatment technologies.

5. *Pretreatment Standards for Existing Sources (PSES).* PSES are designed to prevent the discharge of pollutants that pass through, interfere with, or are otherwise incompatible with the operation of publicly owned treatment works (POTW). They must be achieved within three years of promulgation. The legislative history of the 1977 Act indicates that pretreatment standards are to be technology-based, analogous to the best available technology for removal of toxic pollutants. EPA has generally determined that there is pass through of pollutants if the nationwide average percentage of pollutants removed by a well operated POTW achieving secondary treatment is less than the percent removed by the BAT model treatment system. The General Pretreatment Regulation, which serves as the framework for categorical pretreatment regulations, is found at 40 CFR Part 403.

6. *Pretreatment Standards for New Sources (PSNS).* Like PSES, PSNS are designed to prevent the discharge of pollutants which pass through, interfere with, or are otherwise incompatible with the operation of a POTW. PSNS are to be issued at the same time as NSPS. New indirect dischargers, like new direct dischargers, have the opportunity to incorporate in their plant the best available demonstrated technologies. The Agency considers the same factors in promulgating PSNS as it considers in promulgating PSES.

IV. Methodology and Data Gathering Efforts

The methodology and data gathering efforts used in developing the proposed regulations were summarized in the preamble to the proposed pharmaceutical manufacturing industry regulations (47 FR 53584, November 26, 1982). In summary, before publishing the proposed regulation, the Agency conducted a data collection, analytical screening, and analytical verification program for the pharmaceutical industry. This program stressed the acquisition of data on the presence and treatability of the 129 toxic pollutants and classes of toxic pollutants discussed previously.

Based on the results of that program, comments on the proposed regulations, and additional data gathered or submitted since proposal, EPA identifie several distinct control and treatment technologies that are in use or are capable of being used to treat pharmaceutical wastewaters. For each of these technologies, the Agency: (i) Compiled and analyzed historical and newly-generated data on effluent quality; (ii) identified the reliability and constraints; (iii) considered the non-water quality environmental impacts (including impacts on air quality, solid

waste generation, and energy requirements); and (iv) estimated the costs and economic impacts of applying the technology as a treatment and control system. Costs and economic impacts of the technology options considered are discussed in detail in *Economic Analysis of Effluent Standards and Limitations for the Pharmaceutical Industry* (U.S. EPA, September 1983). A more complete description of the Agency's study methodology, data gathering efforts, and analytical procedures supporting the regulation can be found in the *Development Document for Effluent Limitations Guidelines, New Source Performance Standards, and Pretreatment Standards for the Pharmaceutical Manufacturing Point Source Category* (U.S. EPA, September 1983).

To allow the Agency to respond fully to comments on the proposed rules, the Agency engaged in additional data gathering activities after November of 1982. A major effort involved gathering information on the presence and variability of toxic volatile organics (TVOs) in pharmaceutical raw wastes and treated effluents. In this regard, EPA obtained additonal data on the percentages of process wastewater discharges that are contaminated with TVOs and on the levels of TVOs contained in the contaminated waste streams. To broaden our data base on pass through of TVOs, we also sampled a publicly owned treatment works (POTW) receiving pharmaceutical discharges. The Agency also identified pharmaceutical plants where steam stripping or related technologies are employed and sampled a steam stripper and flash tank used to remove TVOs. EPA incorporated this additonal information into our existing data base and used the expanded data base to reach decisions on regulation of TVO discharges from the pharmaceutical industry.

In some cases, industry comments on our proposed regulations included effluent data on the discharge of toxic, nonconventional, and conventional pollutants. However, these data were often provided in a format that did not allow for proper analysis by the Agency. In those instances, we requested additional information in a format that would allow us to include the data when developing the final regulations.

Detailed discussions of the results of these additional data gathering efforts can be found below and in the final Development Document.

V. Summary of Promulgated Regulations and Changes From Proposal

The final regulations issued today differ from the proposed regulations. The changes are the result of the Agency's review of comments on the proposal and our analysis of additional information obtained to respond to comments. The following includes a review of the proposed regulation, a summary of the changes from proposal to promulgation, and an explanation of the changes.

In brief, EPA is promulgating BPT effluent limitations controlling the discharge of TSS from plants covered under regulations for subcategories A and C and is modifying existing BPT BOD5, COD, and TSS effluent limitations for subcategories B, D, and E. We are also establishing BPT and BAT effluent limitations guidelines, NSPS, PSES, and PSNS controlling cyanide discharges from pharmaceutical plants.

Concurrent with this regulation, EPA is proposing NSPS to control the discharge of two conventional pollutants (BOD5, and TSS) from new pharmaceutical plants.

A. Subcategorization

On November 26, 1982, we proposed to exclude the research-only subcategory (E) from all but BPT regulations. We also collapsed the remaining four subcategories (fermentation—subcategory A, extraction—subcategory B, chemical synthesis—subcategory C, and formulation—subcategory D) into one subcategory for which one set of BAT limitations, NSPS, PSNS, and PSES were proposed.

We received no comments on the exclusion of the research only subcategory from further regulation under BAT, NSPS, PSES, and PSNS. Therefore, for the reasons discussed later in this preamble (see Section VII Pollutants and Subcategories Not Regulated), we have excluded the research only subcategory from development of further regulations beyond BPT.

A number of commenters objected to the proposed establishment of one pharmaceutical subcategory consisting of fermentation, chemical synthesis, extraction, and formulation plants. They explained that there was no need to change the 1976 BPT subcategorization scheme. They maintained that high raw waste generating facilities (fermentation and chemical synthesis plants) should be regulated on a different basis than low raw waste generating facilities (extraction and formulation plants). We received no comments supporting the proposed change in the subcategorization scheme.

In comments on the proposal, the Agency received new plant data which was added to the existing data base. We analyzed data on influent and effluent characteristics of all direct dischargers to determine if the proposed change in subcategorization was appropriate. Our analysis of the most recent data 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, our analyses show that usually the influent and effluent conventional pollutant and COD concentrations and discharge flows of subcategory A and C plants are similar; we also found that these characteristics for subcategory B and D plants are similar. However, we 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. Our analyses indicate that toxic pollutant loads are similar for all four subcategories.

We are also aware that permitting authorities and the regulated industry are familiar with the original subcategorization scheme and the format of the Code of Federal Regulations. Therefore, the Agency has decided to maintain the existing BPT subcategorization scheme. However, because conventional pollutant raw waste characteristics are similar for subcategory A and C plants, conventional pollutant limitations and standards for those plants should be identical. For the same reason, conventional pollutant limitations and standard for subcategory B plants should be identical to those for subcategory D plants. A more detailed discussion of the industry subcategorization scheme can be found in Section IV of the Development Document.

B. BPT for BOD5, TSS, and COD

The Agency proposed a BPT TSS limitation for all subcategories of plants based on a long-term average concentration of 75 mg/l. This limitation was intended to replace the overly stringent BPT TSS limitations for subcategory B, D, and E plants and to establish BPT TSS limitations for A and C subcategory plants. The original overly stringent BPT TSS limitations were based on data from two plants whose operations were not characteristic of the entire range of

operations employed at plants in the B, D, and E subcategories.

One commenter stated that a single number concentration limit for TSS is not appropriate for high raw waste load plants but may be appropriate for low raw waste load plants.

The existing BPT regulations, which are based on the application of biological treatment, require that each pharmaceutical plant, regardless of subcategory, achieve a 90 percent reduction in BOD5. A single number concentration limit for TSS is not consistent with our BPT percent reduction BOD5 limitations, which when converted to long-term average BOD5 effluent concentrations, vary from plant to plant over a wide range (e.g., from about 15 mg/l to almost 400 mg/l). A single number TSS limitation would require some plants to install more advanced treatment than that technology identified as BPT. It would also mean that low raw waste load plants would be able to operate their treatment systems inefficiently and still comply with the proposed single number limitation. After analyzing all available data, the Agency found that effluent TSS concentrations from biological treatment systems usually are greater than corresponding effluent BOD5 concentrations. We found that the median ratio of effluent TSS concentrations to effluent BOD5 concentrations after biological treatment is 1.7 for both the subcategory A and C and the subcategory B and D plant groups. Consequently, the Agency is finalizing BPT TSS limitations for all five subcategories which are equal to a multiple of 1.7 times the existing BPT BOD5 limitations.

The Agency also proposed alternative concentration-based BOD5 and COD BPT limitations for all subcategories. These proposed revisions to BPT were necessitated by the Agency's decision not to change the existing percent reduction-based BPT limitations even though the proposed BCT and BAT limitations were concentration based. Without the proposed modification in BPT BOD5 and COD limitations, some plants would have had concentration-based BCT and BAT limitations that were less stringent than the percent reduction-based BPT limitations. This condition would have been inconsistent with the requirements of the Clean Water Act. No comments were received on these alternative limitations.

The Agency has reviewed the available influent and effluent BOD5 and COD data in the light of our decision to use the original BPT subcategorization scheme. As a result, the Agency is finalizing alternative BOD5 and COD concentration-based limitations for subcategories B, D, and E. Although we are not yet promulgating final BCT limitations for BOD5 or BAT limitations for COD, available data indicate that the alternative BOD5 and COD limitations are appropriate for these subcategories for another reason. These alternative limitations establish minimum concentration levels consistent with EPA's assessment of a realistic estimate of the lowest attainable long-term average BOD5 and COD concentrations representative of the capability of the best practicable control technology currently available in treating pharmaceutical industry wastewaters. Such alternative limitations are not necessary for subcategory A or C because available data indicate that raw waste loads are sufficiently high at chemical synthesis and fermentation plants that limitations as low as the alternative limitations established for subcategories B, D, and E would not be required under BPT.

C. BPT and BAT Effluent Limitations, NSPS, PSES and PSNS for Cyanide

The Agency proposed BPT and BAT effluent limitations guidelines, NSPS, PSES, and PSNS based on in-plant cyanide destruction and biological treatment. These proposed limitations and standards assumed that monitoring would occur at the end-of-pipe. Proposed PSES would have required compliance by July 1, 1984. At proposal, the Agency requested additional data on the performance of cyanide destruction technology in the pharmaceutical industry.

One commenter stated that the proposed cyanide limitations and standards were not sufficiently representative of the production cycle of the industry because the data which were used to derive the limits were obtained during a period of less than normal production. The commenter, at a later date, submitted three additional sets of data to cover periods of normal production. Another commenter complained that a PSES compliance date of July 1, 1984, would be prohibitively difficult to achieve and suggested that the Agency establish a compliance date of three years after promulgation as authorized by the Clean Water Act.

The new data measured both the performance of in-plant cyanide destruction systems directly and the combination of in-plant and biological treatment. EPA is finalizing BPT and BAT effluent limitations guidelines, NSPS, PSES, and PSNS for cyanide based on these new submissions. The regulations include provisions for monitoring either in-plant after cyanide destruction or end-of-pipe.

Section 307(b)(1) provides that PSES shall specify a time for compliance, not to exceed three years from the date of promulgation. This does not create a presumption that three years will necessarily be allowed. However, the Agency has reviewed information on the installation of cyanide destruction technology at pharmaceutical plants. The readjustment of internal processing conditions to segregate contaminated waste streams may require more time than for only the installation of end-of-pipe treatment equipment. Additionally, plants in this and other industries will be installing the treatment equipment suggested as the model technology for this regulation; this may result in delays in engineering, ordering, installing, and operating this equipment. For the above reasons, EPA decided to specify the date for compliance with pharmaceutical industry PSES as three years from the promulgation date of final PSES for cyanide.

D. BAT Effluent Limitations, NSPS, PSES, and PSNS for Toxic Volatile Organics (TVOs)

Toxic volatile organics (TVOs) are those priority pollutants that are readily purged from water because of their high volatility. Many of these compounds are used as industrial solvents. Methylene chloride, benzene, toluene, and chloroform are four toxic volatile organics that are used as solvents in the manufacture of pharmaceutical products.

1. *Direct Dischargers: BAT/NSPS.* At proposal, methylene chloride and all other toxic volatile organics were recommended for exclusion from direct discharger regulations (BAT and NSPS) under the provisions of paragraph 8 of the Settlement Agreement. With the exception of methylene chloride, three has been no change in our rationale for not establishing effluent limitations guidelines and standards for the TVOs. In the case of methylene chloride, we stated that dischargers were controlled by effluent limitations reflecting the best practicable control technology currently available. We received no comments on our proposed exclusion of this toxic pollutant. However, a reexamination of the existing information on the use and discharge of methylene chloride by direct discharging pharmaceutical plants indicates that, in fact, treatable levels of methylene chloride may remain even after the implementation of BPT (i.e., biological treatment).

Available data show that in cases where the concentrations of methylene

chloride discharged to biological treatment systems are greater than 5 mg/l, treatable concentrations of methylene chloride remain in the effluent. Methylene chloride is used in about 15 percent of all fermentation, chemical synthesis, and extraction processes and to a lesser extent in formulation operations. Our data show that 15 of the 51 direct discharging pharmaceutical plants use methylene chloride in their manufacturing processes. For these reasons, we reconsidered our original paragraph 8 determination.

We considered establishing more stringent BAT effluent limitations guidelines for methylene chloride based on in-plant steam stripping technology in addition to biological treatment. This treatment technology would insure that only low effluent concentrations of methylene chloride would be discharged. However, we found that the costs of installing and operating steam strippers to control methylene chloride are not insignificant. We estimate that nine direct discharging plants would incur average capital and average total annual costs of $0.736 million and $0.712 million (1982 dollars), respectively, per plant. We estimate that the installation of steam stripping technology would reduce current discharge levels of methylene chloride by 60,700 pounds per year at these plants. This compares to the 651,000 pounds per year of methylene chloride that are now removed by biological treatment, the best practicable control technology currently available for this industry. We also determined that steam stripping technology is extremely energy intensive and would increase energy use at these nine direct dischargers by the equivalent of 94,300 barrels of oil per year. We project that the average methylene chloride removal cost resulting from the application of steam stripping technology would be $103 per pound, when assuming full value of the recovered solvent.

After considering the relative toxicity of this pollutant in light of these costs, and all the other factors, we have decided not to issue categorical regulations limiting methylene chloride discharges from the pharmaceutical industry based on the addition of treatment technology beyond biological treatment. We have also decided not to establish limitations based on biological treatment because they would not effect a further removal of methylene chloride. Another factor, while not directly a basis for these decisions, confirmed the reasonableness of the weight we accorded to cost and energy factors. We determined that much of the methylene chloride which would be removed by steam stripping will otherwise volatilize during biological treatment. Our data indicate that the volatilized methylene chloride will not be at levels which create a health risk.

Data on the capabilities of steam stripping and biological treatment technologies to reduce the discharge of methylene chloride and on the cost of installing and operating steam strippers to control toxic volatile organics is presented in Section VII of the Development Document. This information may be used by permit writers in developing permit limitations for methylene chloride on a case-by-case basis where necessary.

2. *Indirect Dischargers: PSES, PSNS.* At proposal, we stated that we were considering establishing pretreatment standards to control TVO discharges because available data indicated that pass through of TVOs occurs at POTWs. A standard of 1.2 mg/l for total toxic volatile organics was suggested in the preamble to the proposed rules, pending the availability of adequate supporting data on the performance of steam stripping technology.

One POTW and one State Agency commented that pretreatment standards contolling TVOs should be promulgated. Industry commenters questioned the need for TVO pretreatment standards in view of the low concentrations of toxic volatile organics in POTW effluents. They also questioned the achievability of a 1.2 mg/l discharge level with steam stripping technology.

In the proposed regulation, 17 TVOs were listed as possible candidates for regulation by pretreatment standards. After reexamining all of the available data, we have concluded that, with the exception of methylene chloride and chloroform, these pollutants should be excluded from regulation by the provisions of paragraph 8 of the Settlement Agreement. Thirteen of these pollutants have been excluded because their amount and toxicity, taken together, are so insignificant as not to justify developing uniformly applicable pretreatment regulations (see Appendix E). Of the remaining, there are two (benzene and toluene) which, while not as insignificant, nonetheless are unlikely to pass through POTWs.

To address the issue of pass through, EPA studied 50 well-operated POTWs that use biological treatment to determine the extent to which priority pollutants are reduced by such POTWs. In the case of benzene and toluene, the data indicate that direct discharger median percent reductions exceed POTW median percent reductions by less than 5 percent (100 percent for direct dischargers versus 99 percent for benzene and 97 percent for toluene at POTWs). In light of the fact that EPA had less data in the POTW studies on benzene and toluene than it had for some other pollutants and in light of the variability in analyzing samples for organic priority pollutants at the concentrations typically found in end-of-pipe biological systems at POTWs and pharmaceutical plants, EPA believes that differences of 5 percent or less between the direct discharger and POTW data for benzene and toluene are unlikely to reflect real differences in treatment efficiency. Therefore, EPA has determined that benzene and toluene do not pass through POTWs.

However, a potential interference problem could exist for these two toxic volatile organics because of a potential fire/explosion hazard. Benzene and toluene water mixtures have low flash points. Relatively small concentrations of these solvents in water mixtures (about 180 mg/l) can cause spontaneous combustion in the vapor space above the water mixture under certain conditions. Our latest information indicates that fire/explosions, while not impossible, are unlikely. Benzene and toluene levels above the minimum concentrations required to cause combustion have not been reported in discharges from plants in the pharmaceutical industry. Because pass through does not occur and interference is unlikely, there is no basis for establishing nationally applicable categorical pretreatment standards for benzene or toluene. However, under the general pretreatment regulation, 40 CFR 403.5, an individual POTW may establish pretreatment standards if benzene and toluene discharges from pharmaceutical users result in interference. Section VII of the Development Document contains suggested pretreatment standards for benzene and toluene, based on steam stripping, for consideration by POTWs establishing standards under § 403.5.

At direct discharging pharmaceutical manufacturing plants, chloroform is reduced to levels that are below its treatability through volatilization in biological treatment systems. Therefore, we have excluded chloroform from BAT regulations under the provisions of paragraph 8(a)(iii) of the Settlement Agreement. As for indirect dischargers, we have found that POTWs to which high concentrations of chloroform are discharged achieve high chloroform removal (greater than 95 percent). Therefore, POTWs receiving high

concentrations of chloroform as a result of pharmaceutical discharges are unlikely to experience pass through. For the above reasons, we have decided not to establish pretreatment standards controlling choloroform from indirect discharging pharmaceutical plants.

Through this process, the Agency determined that only methylene chloride was a candidate for national PSES and PSNS regulations. We found that the installation and operation of steam strippers to reduce methylene chloride discharges to POTWs by pharmaceutical plants would result in costs that are not insignificant. We estimate that 25 indirect discharging plants would incur capital and total annual costs of $0.748 million and $0.768 million (1982 dollars), respectively, per plant. We project that one indirect discharging pharmaceutical plant would close if required to install steam stripping technology. Steam strippers are also equally energy intensive at indirect discharging plants as at direct dischargers. We estimate that the operation of steam strippers at the 25 plants would increase energy usage by the equivalent of 315,000 barrels of oil per year. For these reasons and because we concluded that regulation of methylene chloride at direct dischargers is inappropriate, we decided not to establish categorical PSES and PSNS for methylene chloride.

Data on the capabilities of steam stripping technology to reduce the discharge of methylene chloride and on the cost of installing and operating steam strippers to control toxic volatile organics is presented in Section VII of the Development Document. This information may be used by municipalities in developing pretreatment standards for methylene chloride on a case-by-case basis where necessary.

E. New Source Performance Standards for Conventional Pollutants

On November 26, 1982, EPA proposed conventional pollutant new source performance standards that applied uniformly to subcategories A, B, C, and D. Proposed NSPS were based on advanced biological treatment (i.e., biological treatment systems with longer detention times than those considered as the basis of BPT). As discussed previously, we have determined that separate conventional pollutant limitations are appropriate for the subcategory A and C and the subcategory B and D plant groups. We have also identified four pharmaceutical plants where effluent filtration in addition to advance biological treatment is employed. Conventional pollutant discharges from these plants are significantly lower than from plants where only advanced biological treatment is employed. Consequently, the Agency is proposing NSPS based on effluent filtration in combination with advanced biological treatment. For a more detailed explanation of the basis of this decision, see the preamble to the proposed regulation that appears elsewhere in today's **Federal Register**.

F. BAT Limitations and NSPS for COD

The Agency proposed BAT COD concentration limitations that applied uniformly to subcategories A, B, C, and D based on the same technology identified as the best conventional pollutant control technology (BCT) (i.e., add-on biological treatment). NSPS to control COD were proposed based on advanced biological treatment.

One commenter suggested that limitations and standards should be written for specific compounds, if justifiable, rather than regulating additional pollutants through control of COD. Two industry commenters maintained that there are some chemical synthesis plants which have better than the proposed BCT treatment in-place that cannot meet the proposed limitations. Another commenter stated that it was inappropriate to propose COD limitations based on advanced biological treatment for substances which biodegrade slowly or not at all.

The concentrations of many materials that are measured as or contribute to COD are reduced in biological systems by biodegradation or by air stripping and sorption mechanisms; therefore, increased biological treatment system capacity can afford greater removal of these materials. There are some materials, however, that contribute to COD, such as dissolved inorganic salts and some organics, which pass through biological treatment systems without being biodegraded, air stripped, or absorbed. Available data indicate that even after biological treatment system expansion, many subcategory A and C plants would not meet the proposed COD limitations. Additional information on the identity of the pollutants that contribute to COD and on applicable COD removal technologies is required before we can evaluate COD control options. Therefore, the Agency is postponing a final decision on appropriate BAT limitations and NSPS for the nonconventional pollutant COD until a later date. We are continuing our investigation of appropriate COD removal technologies and their costs.

VI. Costs, Economic Impacts, Executive Order 12291, Regulatory Flexibility Analysis, and Small Business Administration (SBA) Loans

A. Cost and Economic Impact

The Agency's economic impact assessment of this regulation is presented in *Economic Analysis of Effluent Standards and Limitations for the Pharmaceutical Industry.* This report details the investment and annual costs for the industry as a whole and for plants covered by the final regulation. Plant costs are engineering estimates for the effluent control systems described in this preamble. The report assesses the impact of effluent control costs in terms of price changes, plant closures, employment effects, and balance of trade effects.

EPA has identified 466 pharmaceutical facilities that are covered by this regulation. An estimated 134 of these plants are zero dischargers and are not expected to incur costs. Of the remaining 332 discharging plants, EPA estimates that nine will incur total investment costs for BPT, BAT, and PSES of $1.47 million, with annual costs of $0.65 million, including depreciation and interest. These costs are expressed in 1982 dollars and are based on the determinations that plants will upgrade their existing treatment systems to comply with BPT, BAT, or PSES, as appropriate. No plant closures are projected as a result of compliance costs for this regulation and, hence, we expect no adverse employment effects on pharmaceutical manufacturing employees. The maximum price increase if all costs were passed on to consumers is less than 0.1 percent for the plants affected by the regulation. Balance of trade effects are nil.

In order to measure the potential economic impacts, a two-step analytical procedure was employed. First, the analysis determined whether a plant's compliance costs exceeded one percent of sales. If the costs did exceed one percent, then the analysis considered information on the firm's financial position, its size, the relative importance of its pharmaceutical line of business, patent protection, and other economic information relevant to assessing the likely impact of the regulation on a firm. If the firm is in a position to pass the costs on to the consumer, due to patent protection, for example, then it is assumed that prices would increase and the plant would remain in operation. If costs cannot be passed on, then based on the above information, a determination was made as to whether a plant might close, a production line

might shut down, or production might be shifted from one plant to another. For the reasons discussed below and after applying this economic impact methodology, the Administrator has determined that the costs of this regulation are justified.

1. *BPT.* BPT regulations for cyanide and TSS are expected to require expenditures at eight plants (cyanide destruction at four plants, TSS control at five plants, with one of these plants requiring both). Total investment and annual costs are estimated to be $1.05 million and $0.39 million, respectively (1982 dollars). The estimated change in price for the affected plants is less than 0.1 percent. No significant economic impacts are projected as a result of BPT.

2. *BAT.* Only cyanide is limited under BAT. Cyanide limits are the same as under BPT. Therefore, no incremental impacts are expected from implementation of BAT.

3. *PSES.* The standard is for the control of cyanide. Only one out of the 277 indirect discharging plants is expected to incur costs; the estimated capital and annual costs are $0.42 million and $0.26 million, respectively (1982 dollars). The expected price change is nil. No significant economic impacts are expected from the PSES cyanide regulation.

4. *NSPS and PSNS.* Only pH and cyanide are limited under NSPS. Since the pH and cyanide limits are the same as under BPT, no incremental impacts will result from implementation of final NSPS. NSPS controlling BOD5 and TSS are being proposed today in a companion notice.

Regulations for indirect discharging new sources (PSNS) are the same as those for existing sources. Therefore, no incremental impacts are expected from implementation of PSNS.

B. Cost Effectiveness

EPA has conducted an analysis of the incremental removal cost per pound equivalent for each toxic pollutant control option. A pound equivalent is calculated by multiplying the number of pounds of pollutant discharged by a weighting factor for that pollutant. The weighting factor is equal to the aquatic life water-quality criterion for a standard pollutant (copper), divided by the aquatic life water-quality criterion for the pollutant being evaluated. The use of "pound equivalent" gives relatively more weight to removal of more highly toxic pollutants. Thus for a given expenditure, the cost per pound equivalent removal would be lower when a highly toxic pollutant is removed than if a less toxic pollutant is removed. This analysis is included in the record of this rulemaking in a document titled "Cost Effectiveness Analysis of Effluent Standards and Limitations for the Pharmaceutical Industry."

C. Executive Order 12291

Executive Order 12291 requires EPA and other agencies to perform regulatory impact analyses of major regulations. Major rules are those which impose an annual cost on the economy of $100 million or more or have certain other economic impacts. This regulation is not a major rule because its annualized cost is less than $100 million and it meets none of the other criteria specified in Section I, paragraph (b) of the Executive Order. The economic impact analysis prepared for this rulemaking satisfies the requirement of the Executive Order for a non-major rule.

D. Regulatory Flexibility Analysis

Pub. L. 96-354 requires EPA to prepare an *Initial Regulatory Flexibility Analysis* for all regulations that have a significant impact on a substantial number of small entities. This analysis may be conducted in conjunction with or as part of other Agency analyses.

Since no firms in the data base are projected to experience significant economic impacts, there is no disproportionate burden on small businesses; therefore, a formal Regulatory Flexibility Analysis is not required.

E. SBA Loans

The Agency is continuing to encourage small pharmaceutical manufacturers to use Small Business Administration (SBA) financing as needed for pollution control equipment. The three basic programs are: (1) The Section 503 Program; (2) the Regular Guarantee Program; and (3) the Guaranteed Pollution Control Bond Program. All the SBA loan programs are open only to businesses that have: (a) Net assets less than $6 million; (b) an average annual after-tax income of less than $2 million; and (c) fewer than 250 employees. The estimated economic impacts for this point source category do not include consideration of financing available through these programs.

The Section 503 Program, as amended in July 1980, allows long-term loans to small and medium sized businesses. These loans are made by SBA approved local development companies. For the first time these companies are authorized to issue Government-backed debentures that are bought by the Federal Financing Bank, an arm of the U.S. Treasury.

Through SBA's Regular Guarantee Program, loans are made available by commercial banks and are guaranteed by the SBA. This program has interest rates equivalent to market rates.

For additional information on the Regular Guarantee and Section 503 Programs, contact your district or local SBA Office. The coordinator at EPA headquarters is Ms. Frances Desselle who may by reached at (202) 382-5373.

For further information and specifics on the Guaranteed Pollution Control Bond Program contact: U.S. Small Business Administration, Office of Pollution Control Financing, 4040 North Fairfax Drive, Rosslyn, Virginia 22203; (703) 235-2902.

VII. Pollutants and Subcategories Not Regulated

Paragraph 8 of the modified Settlement Agreement, approved by the District Court for the District of Columbia on March 9, 1979 (12 ERC 1833), contains provisions authorizing the exclusion from regulation, in certain instances, of toxic pollutants and industry subcategories.

A. Pollutants Excluded

Paragraph 8(a)(iii) of the modified Settlement Agreement allows the Administrator to exclude from regulation toxic pollutants not detected by Section 304(h) analytical methods or other state-of-the-art methods. The toxic pollutants not detected in the effluents of direct discharging pharmaceutical plants and, therefore, excluded from regulation in this industry, are listed in Appendix B of this notice.

Paragraph 8(a)(iii) also allows exclusion of pollutants that are: (1) Detected in the effluent from a small number of sources and uniquely related to those sources; (2) detected in only trace amounts not likely to cause toxic effects; (3) sufficiently controlled by existing technologies; or (4) detected in amounts too small to be effectively controlled by technologies known to the Administrator. Thirty-four different toxic pollutants were found in the effluent of direct discharging pharmaceutical plants during the screening and verification program. Twenty-four of these pollutants (toxic metals and volatile organics) were found at treatable levels only in a small number of instances. In those instances, these levels were attributable to manufacturing activities that are uniquely related to the plants sampled. Another eight toxic pollutants (some phenols and phthalates) were found at or below the treatability limit concentrations determined for existing physical-chemical treatment methods by studies conducted on wastewater from

several industry categories. The 32 pollutants are listed in Appendix C to this notice along with the particular reason for excluding them from regulation. The two remaining toxic pollutants detected in the effluent of direct discharging pharmaceutical plants are cyanide and methylene chloride. EPA is establishing BPT and BAT limitations and NSPS controlling the discharge of cyanide. For the reasons discussed above, EPA is not regulating the discharge of methylene chloride from direct discharging pharmaceutical plants.

Paragraph 8(b)(ii) of the Settlement Agreement authorizes the Administrator to exclude from nationally applicable pretreatment standards a subcategory or category if the toxicity and amount of incompatible pollutants (taken together) introduced by such point sources into POTWs is so insignificant as not to justify developing a national pretreatment regulation. EPA has reviewed available data from indirect dischargers and is excluding the 123 toxic pollutants listed in Appendices D and E from nationally applicable pretreatment standards. Appendix D lists those toxic pollutants not detected in the effluents of indirect dischargers. Appendix E lists those toxic pollutants which, although detected, were not significant enough, in terms of toxicity and amount of incompatible pollutants (taken together), to justify nationally applicable pretreatment standards. EPA is establishing PSES and PSNS controlling the discharge of cyanide. For the reasons discussed previously, EPA is not establishing nationally applicable pretreatment standards for methylene chloride or chloroform.

B. Subcategories Excluded

The Settlement Agreement did not require EPA to regulate the entire pharmaceutical industry. Subcategory E, Pharmaceutical Research, is not mentioned in the Settlement Agreement. Since pharmaceutical research does not involve production and wastewater generation in appreciable quantities on a regular basis, EPA now considers this subcategory outside the province of ordinary industrial guidelines development. Therefore, facilities which conduct pharmaceutical research only are specifically excluded from all limitations and standards in this regulation other than the BPT limitations. Research activities conducted at mixed and single subcategory plants (A, B, C, and D only) will be covered by this regulation because the wastewaters from these activities were studied as part of the technical development of this regulation. However, these activities contribute a very small portion of wastewater to the final effluent of the average production facility.

VIII. Non-Water Quality Aspects of Pollution Control

Eliminating or reducing one form of pollution may cause other environmental problems. 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 compliance with these provisions, EPA has considered the effect of these regulations on air pollution, solid waste generation, and energy consumption. This regulation was reviewed by EPA personnel responsible for non-water quality programs. While it is difficult to balance pollution problems against each other and against energy use, EPA believes that this regulation will best serve often competing national goals.

The following non-water quality environmental impacts (including energy requirements) are associated with the final regulations. The Administrator has determined that the impacts identified below are justified by the benefits associated with compliance with the limitations and standards.

A. Solid Waste

EPA estimates that the total solid waste generated to attain the new BPT TSS limitations will be approximately 138,000 additional pounds per year of wastewater treatment sludge. This is equal to an incremental increase of about 0.3 percent over that currently generated by the pharmaceutical industry to meet existing BPT BOD5 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 pharmaceutical plants under the new BPT TSS limitations 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.

No sludge will be generated as a result of complying with the final pretreatment standards, NSPS, or the BPT and BAT effluent limitations for cyanide.

B. Air Pollution

EPA does not believe that cyanide removal mechanisms will cause the generation of air pollutants; additionally, we do not anticipate that compliance with the modified and new BPT TSS limitations will result in the generation of additional air pollution from pharmaceutical plants.

C. Energy Requirements

EPA estimates that the achievement of the cyanide and the new modified TSS BPT effluent limitations will increase energy consumption by approximately 0.01 percent of present facility use for all plants. We estimate that compliance with PSES to control cyanide discharges to POTWs will increase over-all energy use by 0.07 percent at the affected indirect discharging pharmaceutical plant. Because BAT limitations and NSPS for cyanide are identical to BPT cyanide limitations and because PSNS are identical to PSES, there will be no incremental increase in energy usage resulting from compliance with BAT effluent limitations, NSPS, or PSNS.

IX. Best Management Practices

Section 304(e) of the Clean Water Act authorizes the Administrator to prescribe what have been termed "best management practices" (BMPs). The Agency is not promulgating BMPs for the pharmaceutical industry at this time. However, the existing BPT regulation requires that separable mycelia and solvents not be included in the raw waste load calculations that form the basis of determinations of BPT effluent limitations for BOD5 and COD. (*See* 40 CFR Part 439; 41 FR 50676, November 17, 1976). This rulemaking does not change this requirement.

X. Upset and Bypass Provisions

A recurring issue of concern has been whether industry guidelines should include provisions authorizing noncompliance with effluent limitations during periods of "upset" or "bypass." An upset, sometimes called an "excursion," is an unintentional noncompliance occurring for reasons beyond the reasonable control of the permittee. It has been argued that an upset provision is necessary in EPA's effluent limitations because such upsets will inevitably occur even in properly operated control equipment. Because technology-based limitations are to require only what technology can achieve, it is claimed that liability for such situations is improper. When confronted with this issue, courts have disagreed on whether an explicit upset

or excursion exemption is necessary or whether upset or excursion incidents may be handled through EPA's exercise of enforcement discretion. Compare *Marathon Oil Company* v. *EPA*, 564 F.2d 1253 (9th Cir. 1977) with *Weyerhaeuser* v. *Costle, supra*, and *Corn Refiners Association, et al.* v. *Costle*, No. 78–1069 (8th Cir., April 2, 1979). See also *American Petroleum Institute* v. *EPA*, 540 F.2d 1023 (10th Cir. 1976); *CPC International Inc.* v. *Train*, 540 F.2d 1320 (8th Cir. 1976); *FMC Corp.* v. *Train*, 539 F.2d 973 (4th Cir. 1976).

An upset is an unintentional episode during which effluent limits are exceeded; however, a bypass is an act of intentional noncompliance during which wastewater treatment facilities are circumvented in emergency situations. We have, in the past, included bypass provisions in NPDES permits.

EPA has determined that both upset and bypass provisions should be included in NPDES permits and has promulgated NPDES regulations which include upset and bypass permit provisions. (*See* 40 CFR 122.41, 45 FR 14166 (April 1, 1983).) The upset provision establishes an upset as an affirmative defense to prosecution for violation of technology-based effluent limitations. The bypass provision authorizes bypassing to prevent loss of life, personal injury, or severe property damage. Consequently, although permittees in the pharmaceutical manufacturing industry will be entitled to the upset and bypass provisions incorporated into NPDES permits, this regulation does not address these issues.

XI. Variances and Modifications

The BPT and BAT effluent limitations and NSPS contained in this regulation must be applied in all Federal and State NPDES permits issued to direct dischargers in the pharmaceutical industry. In addition, the pretreatment standards are directly applicable to any indirect dischargers.

For the BPT effluent limitations, the only exception to the binding limitations is EPA's "fundamentally different factors" variance. (*See E. I. duPont de Nemours and Co.* v. *Train*, 430 U.S. 112 (1977); *Weyerhaeuser Co.* v. *Costle, supra.*) This variance recognizes factors concerning a particular discharger which are fundamentally different from the factors considered in this rulemaking. Although this variance clause was set forth in EPA's 1973 to 1976 regulations for specific industries, it is now included in the general NPDES regulations and will not be included in the specific pharmaceutical industry regulations. (*See* the NPDES regulations at 40 CFR Part 125, Subpart D.) The BAT limitations in this regulation are also subject to EPA's "fundamentally different factors" variance.

Indirect discharges subject to PSES and PSNS are eligible for credits for toxic pollutants removed by POTWs. See 40 CFR 403.7; 48 FR 9404 (January 28, 1981). New sources are not eligible for any other statutory or regulatory modification. See *E. I. duPont de Nemours & Co.* v. *Train, supra.*

Indirect dischargers subject to PSES have, in the past, been eligible for the "fundamentally different factors" (FDF) variance. See 40 CFR 403.13. However, on September 20, 1983, the U.S. Court of Appeals for the Third Circuit held that "FDF variances for toxic pollutants are forbidden by the Act," and remanded § 403.13 to EPA. *National Association of Metal Finishers, et al.* v. *EPA*, Nos. 79–2256 *et al.* (3d Circuit, September 20, 1983). EPA is considering the effect of that decision.

In a few cases, information which would affect these PSES may not have been available to EPA or affected parties in the course of this rulemaking. As a result, it may be appropriate to issue specific categorical standards for such facilities, treating them as a separate subcategory with more, or less, stringent standards as appropriate. This will only be done if a different standard is appropriate because of unique aspects of the factors listed in Section 304(b)(2)(B) of the Act: the age of equipment and facilities involved, the process employed, the engineering aspects of applying control techniques, non-water quality environmental impacts (including energy requirements), or the cost of required effluent reductions (but not of ability to pay that cost).

Indirect dischargers and other affected parties may petition the Administrator to examine those factors and determine whether these PSES are properly applicable in specific cases or should be revised. Such petitions *must* contain specific and detailed support data, documentation, and evidence indicating why the relevant factors justify a more, or less, stringent standard, and must also indicate why those factors could not have been brought to the attention of the Agency in the course of this rulemaking. The Administrator will consider such rulemaking petitions and determine whether a rulemaking should be initiated.

XII. Implementation of Limitations and Standards

A. Relationship to NPDES Permits

The BPT and BAT limitations and NSPS in this regulation will be applied to individual pharmaceutical plants through NPDES permits issued by EPA or approved state agencies, under Section 402 of the Act. As discussed in the preceding section of this preamble, these limitations must be applied in all Federal and State NPDES permits except to the extent that variances and modifications are expressly authorized. Other aspects of the interaction between these limitations and NPDES permits are discussed below.

One issue that warrants consideration is the effect of this regulation on the powers of NPDES permit-issuing authorities. The promulgation of this regulation does not restrict the power of any permitting authority to act in any manner consistent with law or these or any other EPA regulations, guidelines, or policy. For example, even if this regulation does not control a particular pollutant, the permit issuer may still limit such pollutant on a case-by-case basis when limitations are necessary to carry out the purposes of the Act. In addition, to the extent that state water quality standards or other provisions of State or Federal law require limitation of pollutants not covered by this regulation (or require more stringent limitations on covered pollutants), such limitations must be applied by the permit issuing authority.

A second topic that warrants discussion is the operation of EPA's NPDES enforcement program, many aspects of which were considered in developing this regulation. We emphasize that although the Clean Water Act is a strict liability statute, the initiation of enforcement proceedings by EPA is discretionary. We have exercised and intend to exercise that discretion in a manner that recognizes and promotes good-faith compliance efforts.

B. Indirect Dischargers

For indirect dischargers, PSES and PSNS are implemented under National Pretreatment Program procedures outlined in 40 CFR 403. The table below may be of assistance in resolving questions about the operation of that program. A brief explanation of some of the submissions indicated on the table follows.

A "request for category determination" is a written request, submitted by an indirect discharger or its POTW, for a determination of which categorical pretreatment standard

applies to the indirect discharger. This assists the indirect discharger in knowing which PSES or PSNS limits it will be required to meet. See 40 CFR 403.6(a).

A "baseline monitoring report" is the first report an indirect discharger must file following promulgation of an applicable standard. The baseline report includes an identification of the indirect discharger, a description of its operations, a report on the flows of regulated streams and the results of sampling analyses to determine levels of regulated pollutants in those streams, a statement of the discharger's compliance or noncompliance with the standard, and a description of any additional steps required to achieve compliance. See 40 CFR 403.12(b).

A "report on compliance" is required of each indirect discharger within 90 days following the date for compliance with an applicable categorical pretreatment standard. The report must indicate the concentration of all regulated pollutants in the facility's regulated process wastestreams; the average and maximum daily flows of the regulated streams; and a statement of whether compliance is consistently being achieved, and if not, what additional operation and maintenance and/or pretreatment is necessary to achieve compliance. See 40 CFR 403.12(d).

A "periodic compliance report" is a report on continuing compliance with all applicable categorical pretreatment standards. It is submitted twice per year (June and December) by indirect dischargers subject to the standards. The report shall provide the concentrations of the regulated pollutants in its discharge to the POTW, the average and maximum daily flow rates of the facility, the methods used by the indirect discharger to sample and analyze the data, and a certification that these methods conform to the methods outlined in the regulations. See 40 CFR 403.12(e).

INDIRECT DISCHARGES SCHEDULE FOR SUBMITTAL AND COMPLIANCE

Item event	Applicable sources	Date or time period	Measured	Item submitted to
Request for category determination.	Existing	60 days	From effective of standard, or from Development document availability.	Director.[1]
	New	[2]		
Baseline monitoring report	All	180 days	From effective date of standard or Final decision on category determination.	Control authority.[3]
Report on compliance	Existing	90 days	From date for final compliance	Control authority.[3]
	New	90 days	From commencement discharge to POTW.	
Periodic compliance reports	All	June and December.		Control authority.[3]

[1] Director = (a) Chief Administrative Officer of a State water pollution control agency with an approved pretreatment program; or (b) EPA Regional Water Division Director, if State does not have an approved pretreatment program.
[2] Prior to commencement of discharge to POTW.
[3] Control Authority = (a) POTW if its pretreatment program has been approved; or (b) Director of State water pollution control agency with an approved pretreatment program or (c) EPA Regional Administrator, if State does not have an approved pretreatment program.

XIII. Public Participation—Responses to Major Comments

Numerous agencies and groups have participated in this study of the pharmaceutical industry. The Agency solicited comments on the proposed rules and on the Development Document and the economic analysis supporting the proposal.

The comment period ended on January 25, 1983. Comments were submitted by one trade association, 11 individual companies, one state agency, two municipalities, and one engineering consultant representing industrial clients.

The Agency held a public hearing on the proposal on January 17, 1983, in Washington D.C. A Technical Workshop was held on January 18, 1983, in Washington, D.C.

Individual public comments received on the proposed regulation and our responses are presented in a report, "Summary of Comments and Responses on the November 1982 Proposed Regulations for the Pharmaceutical Industry," September 1982, which is part of the public record of this rulemaking. A summary of the major comments that are not discussed elsewhere in this preamble and the Agency's responses follow.

1. *Comment:* Effluent limitations should be in the form of treatment removal efficiencies or mass limits of pollutants with concentration limitations being required only in specific cases at the discretion of the local permit writer where the receiving water quality may be a limiting factor.

Response: Effluent limitations guidelines can be in the form of percent reduction, concentration, or production-based mass limitations. Limitations can be based solely on the performance of applicable treatment technologies. However, when the available production data for an industrial category or subcategory can be correlated with pollutant discharges, EPA can develop mass limitations based on both treatment technology performance and production. This latter approach, however, is not appropriate for the pharmaceutical manufacturing point source category because of the large number of different products involved, the constantly changing nature of the product mix, and the lack of an established correlation between pollutant discharge and production. The development of percent reduction limitations requires that influent as well as effluent data descriptive of treatment technology performance be available whereas concentration limitations require only that effluent data be available. Oftentimes, influent data relating to treatment system performance is either not available or is considerably less extensive and descriptive than the effluent data. Both of these considerations influenced the Agency's decision to propose concentration-based limitations for the pharmaceutical industry.

Effluent limitations guidelines whether in the form of percent reduction, concentration, or production-based mass limits are to be used by NPDES permit writers in developing minimum permit requirements. Generally, effluent limitations are converted into mass limitations by permit writers. Permit writers may incorporate more stringent limits such as those required by water quality considerations, but in no case may the permit limits be less stringent (i.e., allow a greater pollutant discharge) than those that are indicated by an applicable technology-based effluent limitations guideline.

2. *Comment:* On June 8, 1982, EPA issued a final rulemaking which modified effluent limitations guidelines for pH for all industrial dischargers. The final rule required compliance 99 percent of the time and limited individual excursions to 60 minutes. We believe that EPA has inadvertently failed to include this change in the proposed pharmaceutical guidelines and therefore request EPA to incorporate this change into the guidelines.

Response: The applicability of the final rule cited by the commenter (see 47 FR 34534–34537, June 4, 1982) is contingent on whether a permittee is required, or has the option, to monitor

continuously the pH of its wastewater as specified by the conditions of the permittee's National Pollutant Discharge Elimination System (NPDES) permit. If the industrial discharger's NPDES permit does not contain a requirement or an option for the permittee to monitor pH continuously, then the monthly and individual excursion limitations of that rule are not applicable. Thus, the rule applies only to those industrial dischargers with an NPDES permit requirement or option to monitor continuously the pH of their wastewater. The modified pH rule for continuous monitoring is currently applicable to permittees having this requirement or option (see 40 CFR 401.17). It is not necessary that this modified rule be explicitly stated in all categorical regulations.

3. *Comment:* Several commenters requested additional time to comment on the grounds that EPA, in these proposed rules and accompanying documents, has for the first time released substantial portions of the information on which certain of the proposed rules are based, and has materially revised other portions of the information on which other portions of the proposed rules are based.

Response: After consideration of the amount and complexity of the new information released in the proposed rulemaking and the fact that all of the information supporting the proposed regulations was available to the public at the time that the proposed regulations were published in the **Federal Register**, we concluded that a 60-day comment period was an adequate time period for commenting on the proposed regulations. The Agency has allowed extensions of comment periods on some proposal regulations due to certain special circumstances surrounding those rulemakings. However, no such circumstances were present in the pharmaceutical rulemaking. Therefore, the Agency concluded that an extension of the comment period for this rulemaking was not appropriate.

EPA received several comments after the close of the official comment period. The Agency has evaluated and responded to these comments.

4. *Comment:* One commenter stated that TSS limits are inappropriate for plants discharging to rivers, such as the Mississippi, presumably because they are naturally turbid. The commenter recommended that permit writers be allowed to disregard or modify TSS limitations.

Response: We have not made any changes in response to this comment. Section 304 of the Act requires that effluent limitations guidelines be based on the application of control and treatment technology. EPA may not consider receiving water quality in developing such guidelines. Accordingly, BPT TSS limitations are based on the application of currently available technology, not on water quality considerations. Since receiving water quality is not a factor which is considered in establishing categorical limitations, it follows that it cannot be considered by the permit writer as a basis for a fundamentally different factors (FDF) variance.

5. *Comment:* One commenter objected to the fact that "new sources" were defined in terms of plants whose construction commences after proposal of a new source performance standard, rather than after final promulgation. The commenter noted that there may be changes in the standard between proposal and final promulgation.

Response: The definition of "new source" in Appendix A to the proposal is a shortened version of the definition of new source established in EPA's NPDES permit regulations (40 CFR 122.2, April 1, 1983, 48 FR 14146). To avoid confusion, we have revised the definition in Appendix A.

6. *Comment:* Since regulations controlling the discharge of BOD*5* are included in the proposed regulation, we question the need for COD limitations. What additional pollutants is EPA trying to control with COD limitations? We consider these limitations to be duplicative in nature and unwarranted.

Response: Many materials that are measured as or contribute to COD biodegrade slowly or not at all, while those materials which contribute to BOD*5* are, by definition, biodegradable. Removal of COD in a biological treatment system is accomplished to some extent by biodegradation but also by incidental removal mechanisms such as air stripping and sorption. Since the extent to which any of these mechanisms operates to remove COD depends in part on the size of the biological treatment system, any increase in the capacity of a biological treatment system should result in greater removal of these materials. The Agency recognizes that there are also some pollutants measured by COD, such as salts and some solvents, which do not biodegrade.

The 1976 BPT regulation requires all subcategories to achieve a 74 percent reduction of COD from raw waste levels and, in addition, specifies that separable solvents be removed by in-plant control methods prior to measurement of raw waste COD levels. The purpose of the existing BPT COD limitations is to limit the discharge of those materials which biodegrade slowly or not at all by first prohibiting the inclusion of certain non-biodegradable materials (e.g., some solvents) in raw waste streams and by accounting for the incidental removal of COD that occurs in biological treatment systems. More stringent BAT limitations and NSPS for COD based on add-on biological treatment were included in the proposed regulation of November 26, 1982. We intend to issue final BAT limitations and NSPS for COD for all subcategories after reviewing additional data on the pollutants which constitute COD in pharmaceutical plants and on the cost of their removal. The Agency continues to believe that limitations controlling the discharge of COD are appropriate and not duplicative in nature.

7. *Comment:* EPA has proposed to apply broad categorical limits for an individual pollutant, cyanide, that may be present in only a few operations. By proposing a limit for cyanide, EPA will require all pharmaceutical plants to expend resources to monitor for cyanide whether or not cyanide is used or generated in the manufacturing process. At a minimum, EPA's action will force certain dischargers to request a fundamentally different factors (FDF) variance at the time of permit re-issuance to avoid unnecessary monitoring requirements.

Response: EPA agrees with the commenter that if cyanide is not used or generated in the manufacturing process, dischargers should not be required to monitor for cyanide. Therefore, the final regulations allow facilities not using or generating cyanide to certify to that effect instead of monitoring for cyanide. Permit issuing authorities may find it necessary to require that specific monitoring programs be instituted at individual plants if cyanide contamination is suspected.

XIV. Availability of Technical Information

The basis for this regulation is detailed in four major documents. Analytical methods are discussed in *Sampling and Analysis Procedures for Screening of Industrial Effluents for Priority Pollutants* (U.S. EPA, April 1977). EPA's technical conclusions are detailed in *Development Document for Effluent Guidelines, New Source Performance Standards, and Pretreatment Standards for the Pharmaceutical Manufacturing Point Source Category* (USEPA, September 1983). The Agency's economic analysis is presented in *Economic Analysis of Effluent Standards and Limitations for the Pharmaceutical Industry* (USEPA,

September 1983). A summary of the public comments received on the proposed regulation is presented in a report "Summary of Responses to Comment on the Proposed Pharmaceutical Manufacturing Industry Regulations," which is a part of the public record for this regulation. On November 28, 1983, copies of the technical development document and the economic analysis will be available for public review in EPA's Public Information Reference Unit, Room 2404 (Rear) in the EPA Library, 401 M Street, SW., Washington, D.C. Copies of the technical and economic documents may also be obtained from the National Technical Information Service (NTIS), Springfield, Virginia 22161, (703) 487–4600. A notice will be published in the **Federal Register** announcing the availability of these documents from NTIS. (This should occur on or before December 27, 1983).

Additional information concerning the economic impact analysis may be obtained from Mr. Joseph Yance, Economic Analysis Staff (WH–586), U.S. Environmental Protection Agency, 401 M Street, SW., Washington, D.C. 20460 or by calling (202) 382–5397. Technical information may be obtained by writing to Dr. Frank Hund, Effluent Guidelines Division (WH–552), U.S. Environmental Protection Agency, 401 M Street, SW., Washington, D.C. 20460 or by calling (202) 382–7182.

XV. Office of Management and Budget (OMB) Review

This notice was submitted to the Office of Management and Budget for review as required by Executive Order 12291. Any commments from OMB to EPA and any EPA response to those comments are available for public inspection through contacting Dr. Frank Hund at the address listed at the beginning of this notice.

This regulation contains provisions in §§ 439.14–439.17, 439.24–439.27, 439.34–439.37, and 439.44–439.47 which allow facilities not using or generating cyanide to certify to that effect instead of monitoring for cyanide. The information collection requirements in ths rule have been submitted to OMB under provisions of the Paperwork Reduction Act of 1980, 44 U.S.C. 3501 *et seq.* They are not effective until OMB approves them and a technical amendment to that effect is published in the **Federal Register.**

XVI. List of Subjects in 40 CFR Part 439

Drugs, Waste treatment and disposal, Water pollution control.

Dated: September 30, 1983.

William D. Ruckelshaus,

Administrator.

Appendix A—Abbreviations, Acronyms, and Other Terms Used in this Notice

Act—The Clean Water Act.

Agency—The U.S. Environmental Protection Agency.

BAT—The best available technology economically achievable, under Section 304(b)(2)(B) of the Act.

BCT—The best conventional pollutant control technology, under Section 304(b)(4) of the Act.

BMP—Best management practices, under Section 304(e) of the Act.

BPT—The best practicable control technology currently available, under Section 304(b)(1) of the Act.

Clean Water Act—The Federal Water Pollution Control Act Amentments of 1972 (33 U.S.C. 1251 *et seq.*), as amended by the Clean Water Act of 1977 (Pub. L. 95–217).

Direct Discharger—A facility where wastewaters are discharged or may be discharged into waters of the United States.

Indirect Discharger—A facility where wastewaters are discharged or may be discharged into a publicly owned treatment works.

New Sources—Industrial facilities which are "new sources" under the definition in Section 306 of the Act.

NPDES Permit—A National Pollutant Discharge Elimination System permit issued under Section 402 of the Act.

NSPS—New source performance standards, under Section 306 of the Act.

POTW or POTWs—Publicly owned treatment works.

PSES—Pretreatment standards for existing sources of indirect discharges, under Section 307(b) of the Act.

PSNS—Pretreatment standards for new sources of indirect discharges, under Section 307 (b) and (c) of the Act.

RCRA—Resource Conservation and Recovery Act (Pub. L. 94–580) of 1976, as amended, 42 U.S.C. 6901 *et seq.*

Appendix B—Toxic Pollutants Not Detected in the Effluent of Direct Dischargers

acenaphthene
acrylonitrile
benzidine
1,1-dichloroethane
1,2,4-trichlorobenzene
hexachlorobenzene
hexachloroethane
1,1,2-trichloroethane
1,1,2,2-tetrachloroethane
chloroethane
bis(2-chloroethyl) ether
2-chloroethyl vinyl ether
2-chloronapthalene
2,4,6-trichlorophenol
parachlorometa cresol
2-chlorophenol
1,3-dichlorobenzene
1,4-dichlorobenzene
3,3'-dichlorobenzidine
1,1-dichloroethylene
1,2-trans-dichloroethylene
2,4-dichlorophenol
1,2-dichloropropane
1,3-dichloropropylene
2,4-dinitrotoluene
2,4-dimethyl phenol
2,6-dinitrotoluene
1,2-diphenlhydrazine
fluoranthene
4-chlorophenyl phenyl ether
4-bromophenyl phenyl ether
bis(2-chloroethoxy) methane
methyl bromide
dichlorobromomethane
chlorodibromethane
hexachlorobutadiene
hexachlorocyclopentadiene
isophorone
naphthalene
nitrobenzene
2-nitrophenol
4,6-dinitro-o-cresol
N-nitrosodimethylamine
N-nitrosodiphenylamine
N-nitrosodi-n-propylamine
pentachlorophenol
butyl benzyl phthalate
di-n-octyl phthalate
dimethyl phthalate
benzo(a)anthracene
benzo(a)pyrene
3,4-benzofluoranthene
benzo(k)fluoranthane
chrysene
acenaphthylene
anthracene
benzo(ghi)perylene
fluorene
phenanthrene
dibenzo(a,h)anthracene
indeno(1,2,3-c,d)pyrene
pyrene
aldrin
dieldrin
chlordane
4,4'-DDT
4,4'-DDE
4,4'-DDD
alpha-endosulfan
beta-endosulfan
endosulfan sulfate
endrin
endrin aldehyde
heptachlor
heptachlor epoxide
alpha-BHC
beta-BHC
gamma-BHC (lindane)
delta-BHC
PCB–1242
PBC–1254

PCB–1221
PCB–1232
PCB–1248
PCB–1260
PCB–1016
toxaphene
asbestos (fibrous)
beryllium (total)
2,3,7,8-tetrachloro-dibenzo-p-dioxin (TCDD)

Appendix C—Toxic Pollutants Detected in Treated Effluents of Direct Dischargers: (1) From a Small Number of Sources, (2) Detected in Only Trace Amounts, (3) Sufficiently Controlled by Existing Technologies, or (4) Detected in Amounts Too Small to be Effectively Controlled by Technologies Known to the Administrator

Pollutant and basis for exclusion

Acrolein	1
Benzene	3
Bromoform	1
Carbon tetrachloride	2
1,2-dichloroethane	3
1,1,1-trichloroethane	3
Chloroform	3
Ethylbenzene	3
Bis(2-chloroisopropyl) ether	1
Methyl chloride	3
4-nitrophenol	3
2,4-dinitrophenol	3
Phenol	3
Bis(2-ethylhexyl) phthalate	4
Di-n-butyl phthalate	4
Diethyl phthalate	4
Tetrachloroethylene	2
Toluene	3
Trichloroethylene	3
Vinyl chloride	2
Antimony	4
Arsenic	4
Cadmium	4
Chromium	4
Copper	4
Lead	4
Mercury	4
Nickel	4
Selenium	4
Silver	4
Thallium	4
Zinc	4

Appendix D—Toxic Pollutants Not Detected in the Effluent of Indirect Dischargers

acenaphthene
benzidine
1,2,4-trichlorobenzene
hexachlorobenzene
hexachloroethane
1,1,2-trichloroethane
1,1,2,2-tetrachloroethane
chloroethane
bis(2-chloroethyl) ether
2-chloroethyl ether
2-chloronapthalene
2,4,6-trichlorophenol
parachlorometa cresol
2-chlorophenol
1,3-dichlorobenzene
1,4-dichlorobenzene
3,3'-dichlorobenzidine
2,4-dichlorophenol
1,2-dichloropropane
1,3-dichloropropylene
2,4-dinitrotoluene
2,6-dinitrotoluene
1,2-diphenlhydrazine
fluoranthene
4-Chlorophenyl phenyl ether
4-bromophenyl phenyl ether
bis(2-chloroethoxy) methane
methyl bromide
dichlorobromomethane
chlorodibromethane
hexachlorobutadiene
hexachlorocyclopentadiene
isophorone
naphthalene
nitrobenzene
4-nitrophenol
2,4-dinitro phenol
4,6-dinitro-o-cresol
N-nitrosodi-n-propylamine
pentachlorophenol
butyl benzyl phthalate
di-n-octyl phthalate
dimethyl phthalate
benzo(a)anthracene
benzo(a)pyrene
3,4-benzofluoranthene
benzo(k)fluoranthane
chrysene
acenaphthylene
anthracene
benzo(ghi)perylene
phenanthrene
dibenzo(a,h)anthracene
indeno (1,2,3-c,d)pyrene
pyrene
aldrin
dieldrin
chlordance
4,4'-DDT
4,4'-DDE
4,4'-DDD
alpha-endosulfan
beta-endsulfan
endosulfan sulfate
endrin
endrin aldehyde
heptachlor
heptachlor epoxide
alpha-BHC
beta-BHC
gamma-BHC (lindane)
delta-BHC
PCB–1242
PCB–1254
PCB–1221
PCB–1232
PCB–1248
PCB–1260
PCB–1016
toxaphene
asbestos (fibrous)
beryllium
2,3,7,8-tetrachloro-dibenzo-p-dioxin (TCDD)

Appendix E—Toxic Pollutants Detected in the Effluent of Indirect Dischargers Whose Toxicity and Amount (Taken Together) Are So Insignificant As Not To Justify Developing Pretreatment Regulations

*acrolein
*acrylonitrile
benzene
*carbon tetrachloride
*chlorobenzene
methyl chloride
1,2-dichlorobenzene
*1,2-dichloroethane
*1,1, 1-trichloroethane
*1,1-dichloroethane
*1,1-dichloroethylene
*1,2-trans-dichloroethylene
*ethylbenzene
*bromoform
*tetrachloroethylene
toluene
*trichloroethylene
2,4-dimethylphenol
2-nitrophenol
N-nitrosodiphenylamine
phenol
bis(2-ethyl hexyl) phthalate
diethyl phthalate
fluorene
antimony
arsenic
cadmium
chromium
copper
lead
mercury
nickel
selenium
silver
thallium
zinc

*Volatile organics identified at proposal as potential candidates for categorical pretreatment standards (47 FR 53584).

Part 439 of Title 40 is revised to read as follows:

PART 439—PHARMACEUTICAL MANUFACTURING POINT SOURCE CATEGORY

General Provisions

Sec.
439 Applicability.
439.1 General definitions.
439.2 Monitoring requirements.

Subpart A—Fermentation Products Subcategory

439.10 Applicability; description of the fermentation products subcategory.
439.11 Specialized definitions.
439.12 Effluent limitations representing the degree of effluent reduction attainable by

Sec.
the application of the best practicable control technology currently available (BPT).
439.13 Effluent limitations representing the degree of effluent reduction attainable by the application of the best conventional pollutant control technology (BCT). [Reserved]
439.14 Effluent limitations representing the degree of effluent reduction attainable by the application of the best available technology economically achievable (BAT).
439.15 New source performance standards (NSPS).
439.16 Pretreatment standards for existing sources (PSES):
439.17 Pretreatment standards for new sources (PSNS).

Subpart B—Extraction Products Subcategory

439.20 Applicability; description of the extraction products subcategory.
439.21 Specialized definitions.
439.22 Effluent limitations representing the degree of effluent reduction attainable by the application of the best practicable control technology currently available (BPT).
439.23 Effluent limitations representing the degree of effluent reducton attainable by the application of the best conventional pollutant control technology (BCT). [Reserved]
439.24 Effluent limitations representing the degree of effluent reduction attainable by the application of the best available technology economically achievable (BAT).
439.25 New source performance standards (NSPS).
439.26 Pretreatment standards for existing sources (PSES).
439.27 Pretreatment standards for new sources (PSNS).

Subpart C—Chemical Synthesis Products Subcategory

439.30 Applicability; description of the chemical synthesis products subcategory.
439.31 Specialized definitions.
439.32 Effluent limitations representing the degree of effluent reduction attainable by the application of the best practicable control technology currently available (BPT).
439.33 Effluent limitations representing the degree of effluent reduction attainable by the application of the best conventional pollutant control technology (BCT). [Reserved]
439.34 Effluent limitations representing the degree of effluent reduction attainable by the application of the best available technology economically achievable (BAT).
439.35 New source performance standards (NSPS).
439.36 Pretreatment standards for existing sources (PSES).
439.37 Pretreatment standards for new sources (PSNS).

Subpart D—Mixing/Compounding and Formulation Subcategory

Sec.
439.40 Applicability; description of the mixing/compounding and formulation subcategory.
439.41 Specialized definitions.
439.42 Effluent limitations representing the degree of effluent reduction attainable by the application of the best practicable control technology currently available (BPT).
439.43 Effluent limitations representing the degree of effluent reduction attainable by the application of the best conventional pollutant control technology (BCT). [Reserved]
439.44 Effluent limitations representing the degree of effluent reduction attainable by the application of the best available technology economically achievable (BAT).
439.45 New source performance standards (NSPS).
439.46 Pretreatment standards for existing sources (PSES).
439.47 Pretreatment standards for new sources (PSNS).

Subpart E—Research Subcategory

439.50 Applicability; description of the research subcategory.
439.51 Specialized definitions.
439.52 Effluent limitations representing the degree of effluent reduction attainable by the application of the best practicable control technology currently available (BPT).
439.53 Effluent limitations representing the degree of effluent reduction attainable by the application of the best conventional pollutant control technology (BCT). [Reserved]
439.54 Effluent limitations representing the degree of effluent reduction attainable by the application of the best available technology economically achievable (BAT). [Reserved]
439.55 New source performance standards (NSPS). [Reserved]
439.56 Pretreatment standards for existing sources (PSES). [Reserved]
439.57 Pretreatment standards for new sources (PSNS). [Reserved]

Authority: Sec. 301, 304 (b), (c), (e), and (g), 306 (b) and (c), 307 (b) and (c), and 501 of the Clean Water Act (the Federal Water Pollution Control Act Amendments of 1972, as amended by the Clean Water Act of 1977) (the "Act"); 33 U.S.C. 1311, 1314 (b), (c), (e), and (g), 1316 (b) and (c), 1317 (b) and (c), and 1361; 86 Stat. 816, Pub. L. 92–500; 91 Stat. 1567, Pub. L. 95–217.

General Provisions

§ 439 Applicability.

This part applies to any pharmaceutical manufacturing facility which discharges or may discharge process wastewater pollutants to the waters of the United States, or which introduces or may introduce process wastewater pollutants into a publicly owned treatment works.

§ 439.1 General definitions.

In addition to the definitions set forth in 40 CFR Part 401, the following definitions apply to this part:

(a) The term "maximum 30 day average" shall mean the maximum average of daily values for 30 consecutive days.

(b) The term "cyanide destruction unit" shall mean a treatment system designed specifically to remove cyanide.

§ 439.2 Monitoring requirements.

Unless otherwise noted, self-monitoring will be conducted at the final effluent discharge point.

Subpart A—Fermentation Products Subcategory

§ 439.10 Applicability; description of the fermentation products subcategory.

The provisions of this subpart are applicable to discharges resulting from the manufacture of pharmaceuticals by fermentation.

§ 439.11 Specialized definitions.

For the purpose of this subpart:

(a) Except as provided below, the general definitions, abbreviations, and methods of analysis set forth in 40 CFR Part 401 and 439.01 shall apply to this subpart.

(b) The term "product" shall mean pharmaceutical products derived from fermentation processes.

§ 439.12 Effluent limitations representing the degree of effluent reduction attainable by the application of the best practicable control technology currently available (BPT).

Except as provided in 40 CFR 125.30 through 125.32, any existing point source subject to this subpart must achieve the following effluent limitations representing the degree of effluent reduction attainable by the application of the best practicable control technology currently available (BPT).

(a) The following limitations establish the quantity or quality of pollutants or pollutant properties, controlled by this paragraph, which may be discharged by a fermentation products plant from a point source subject to the provisions of this paragraph after application of the best practicable control technology currently available:

(1) The allowable effluent discharge limitation for the daily average mass of BOD*5* in any calendar month shall be expressed in mass per unit time and shall specifically reflect not less than 90% reduction in the long term daily average raw waste content of BOD*5* multiplied by a variability factor of 3.0.

(2) The allowable effluent discharge limitation for the daily average mass of COD in any calendar month shall be expressed in mass per unit time and shall specifically reflect not less than 74 percent reduction in the long term daily average raw waste content of COD multiplied by a variability factor of 2.2.

(3) The long term daily average raw waste load for the pollutants BOD5 and COD is defined as the average daily mass of each pollutant discharged in the influent to the wastewater treatment system over a 12 consecutive month period within the most recent 36 months, which shall include the greatest production effort.

(4) To assure equity in regulating discharges from the point sources covered by this subpart of the point source category, calculation of raw waste loans of BOD5 and COD for the purpose of determining NPDES permit limitations (i.e., the base numbers to which the percent reductions are applied) shall exclude any waste load associated with separable mycelia and solvents in those raw waste loads, except that residual amounts of mycelia and solvents remaining after the practice of recovery and/or separate disposal or reuse may be included in the calculation of the raw waste loads. These practices of removal, disposal, or reuse include physical separation and removal of separable mycelia, recovery of solvents from waste streams, incineration of concentrated solvent waste streams (including tar still bottoms), and broth concentration for disposal other than to the treatment system. This regulation does not prohibit inclusion of such waste in the raw waste loads in fact, nor does it mandate any specific practice, but rather describes the rationale for determining the permit conditions. These limits may be achieved by any of several or a combination thereof of programs and practices.

(5) The pH shall be within the range of 6.0–9.0 standard units.

(6) The allowable effluent discharge limitation for the daily average mass of TSS in any calendar month shall be 1.7 times the BOD5 limitation determined in paragraph (a)(1) of this section.

(7) For those plants using or generating cyanide in the manufacturing process, the allowable effluent discharge for cyanide is shown below.

(i)

Pollutant or pollutant property	BPT Effluent limitations	
	Maximum for any 1 day	Average of daily values for 30 consecutive days
	Milligrams per liter (mg/l)	
Total cyanide	33.5	9.4

(ii) If all cyanide-containing waste streams are diverted to a cyanide destruction unit and the effluent from the cyanide destruction unit is discharged to a biological treatment system, self-monitoring must be conducted after cyanide treatment and before dilution with other streams. Alternatively, self-monitoring may be conducted at the final effluent discharge point, if the daily maximum cyanide limitation is multiplied by 0.18, the maximum 30 day average cyanide limitation is multiplied by 0.35, and both limitations are adjusted based on the dilution ratio of the cyanide-contaminated waste stream flow to the total process wastewater discharge flow. However, if all cyanide-containing waste streams are not treated in a cyanide destruction unit or if the effluent from the cyanide destruction unit is not discharged to a biological treatment system, self-monitoring must be conducted at the final effluent discharge point and the daily maximum cyanide limitation must be multiplied by 0.18, the maximum 30 day average cyanide limitation must be multiplied by 0.35, and both limitations must be adjusted based on the dilution ratio of the cyanide-contaminated waste stream flow to the total process wastewater discharge flow. Permittees not using or generating cyanide must certify to the permit-issuing authority that they are not using or generating this compound.

(b) Dilution to meet the above effluent limitations may not be practiced.

§ 439.13 Effluent limitations representing the degree of effluent reduction attainable by the application of the best conventional pollutant control technology (BCT). [Reserved]

§ 439.14 Effluent limitations representing the degree of effluent reduction attainable by the application of the best available technology economically achievable (BAT).

(a) Except as provided in 40 CFR 125.30 through 125.32, any existing point source subject to this subpart where cyanide is used or generated in the manufacturing process must achieve the following effluent limitations representing the degree of effluent reduction attainable by the application of the best available technology economically achievable (BAT).

(1)

Pollutant or pollutant property	BAT Effluent limitations	
	Maximum for any 1 day	Average of daily values for 30 consecutive days
	Milligrams per liter (mg/l)	
Total cyanide	33.5	9.4
COD	(1)	(1)

[1] Reserved.

(2) If all cyanide-containing waste streams are diverted to a cyanide destruction unit and the effluent from the cyanide destruction unit is discharged to a biological treatment system, self-monitoring must be conducted after cyanide treatment and before dilution with other streams. Alternatively, self-monitoring may be conducted at the final effluent discharge point, if the daily maximum cyanide limitation is multiplied by 0.18, the maximum 30 day average cyanide limitation is multiplied by 0.35, and both limitations are adjusted based on the dilution ratio of the cyanide-contaminated waste stream flow to the total process wastewater discharge flow. However, if all cyanide-containing waste streams are not treated in a cyanide destruction unit or if the effluent from the cyanide destruction unit is not discharged to a biological treatment system, self-monitoring must be conducted at the final effluent discharge point and the daily maximum cyanide limitation must be multiplied by 0.18, the maximum 30 day average cyanide limitation must be multiplied by 0.35, and both limitations must be adjusted based on the dilution ratio of the cyanide-contaminated waste stream flow to the total process wastewater discharge flow. Permittees not using or generating cyanide must certify to the permit-issuing authority that they are not using or generating this compound.

(b) Dilution in order to meet the above effluent limitations may not be practiced.

§ 439.15 New source performance standards (NSPS).

(a) The following standards of performance establish the quantity or quality of pollutants or pollutant properties, controlled by this section, which may be discharged by a new source subject to the provisions of this subpart.

(1)

Pollutant or pollutant property	NSPS	
	Maximum for any 1 day	Average of daily values for 30 consecutive days
	Milligrams per liter (mg/l)	
Total cyanide	33.5	9.4
BOD5	(1)	(1)
TSS	(1)	(1)
COD	(1)	(1)
pH	(2)	(2)

[1] Reserved.
[2] Within the range of 6.0 to 9.0 at all times.

(2) If all cyanide-containing waste streams are diverted to a cyanide destruction unit and the effluent from the cyanide destruction unit is discharged to a biological treatment system, self-monitoring must be conducted after cyanide treatment and before dilution with other streams. Alternatively, self-monitoring may be conducted at the final effluent discharge point, if the daily maximum cyanide standard is multiplied by 0.18, the maximum 30 day average cyanide standard is multiplied by 0.35, and both standards are adjusted based on the dilution ratio of the cyanide-contaminated waste stream flow to the total process wastewater discharge flow. However, if all cyanide-containing waste streams are not treated in a cyanide destruction unit or if the effluent from the cyanide destruction unit is not discharged to a biological treatment system, self-monitoring must be conducted at the final effluent discharge point and the daily maximum cyanide standard must be multiplied by 0.18, the maximum 30 day average cyanide standard must be multiplied by 0.35, and both standards must be adjusted based on the dilution ratio of the cyanide-contaminated waste stream flow to the total process wastewater discharge flow. Only facilities where cyanide is used or generated in the manufacturing process are subject to cyanide standards. Permittees not using or generating cyanide must certify to the permit-issuing authority that they are not using or generating this compound.

(b) Dilution in order to meet the above standards may not be practiced.

§ 439.16 Pretreatment standards for existing sources (PSES).

(a) Except as provided in 40 CFR 403.7 and 403.13, any existing source subject to this subpart that introduces pollutants into a publicly owned treatment works must comply with 40 CFR Part 403 and by October 27, 1986, where cyanide is used or generated in the manufacturing process, must achieve the following pretreatment standards for existing sources (PSES).

(1)

Pollutant or pollutant property	PSES	
	Maximum for any 1 day	Average of daily values for 30 consecutive days
	Milligrams per liter (mg/l)	
Total cyanide	33.5	9.4

(2) If all cyanide-containing waste streams are diverted to a cyanide destruction unit, self-monitoring for cyanide must be conducted after cyanide treatment and before dilution with other streams. Alternatively, self-monitoring may be conducted at the final effluent discharge point, if the cyanide standard is adjusted based on the dilution ratio of contaminated waste stream flow to the total process wastewater discharge flow. However, if all cyanide-containing waste streams are not treated, self-monitoring must be conducted at the final effluent discharge point and the cyanide standard must be adjusted based on the dilution ratio of contaminated waste stream flow to the total process wastewater discharge flow. Indirect dischargers not using or generating cyanide must certify to the publicly owned treatment works that they are not using or generating this compound.

(b) Dilution in order to meet the above standards may not be practiced.

§ 439.17 Pretreatment standards for new sources (PSNS).

(a) Except as provided in 40 CFR 403.7, any new source subject to this subpart that introduces pollutants into a publicly owned treatment works must comply with 40 CFR Part 403 and where cyanide is used or generated in the manufacturing process, must achieve the following pretreatment standards for new sources (PSNS).

(1)

Pollutant or pollutant property	PSNS	
	Maximum for any 1 day	Average of daily values for 30 consecutive days
	Milligrams per liter (mg/l)	
Total Cyanide	33.5	9.4

(2) If all cyanide-containing waste streams are diverted to a cyanide destruction unit, self-monitoring for cyanide must be conducted after cyanide treatment and before dilution with other streams. Alternatively, self-monitoring may be conducted at the final effluent discharge point, if the cyanide standard is adjusted based on the dilution ratio of contaminated waste stream flow to the total process wastewater discharge flow. However, if all cyanide-containing waste streams are not treated, self-monitoring must be conducted at the final effluent discharge point and the cyanide standard must be adjusted based on the dilution ratio of contaminated waste stream flow to the total process wastewater discharge flow. Indirect dischargers not using or generating cyanide must certify to the publicly owned treatment works that they are not using or generating this compound.

(b) Dilution in order to meet the above standards may not be practiced.

Subpart B—Extraction Products Subcategory

§ 439.20 Applicability; description of the extraction products subcategory.

The provisions of this subpart are applicable to discharges resulting from the manufacture of pharmaceuticals by extraction.

§ 439.21 Specialized definitions.

For the purpose of this subpart:

(a) Except as provided below, the general definitions, abbreviations, and methods of analysis set forth in 40 CFR Part 401 and 439.01 shall apply to this subpart.

(b) The term "product" shall mean biological and natural extraction products. This subcategory shall include blood fractions, vaccines, serums, animal bile derivatives, endocrine products, and isolation of medicinal products, such as alkaloids, from botanical drugs and herbs.

§ 439.22 Effluent limitations representing the degree of effluent reduction attainable by the application of the best practicable control technology currently available (BPT).

Except as provided in 40 CFR 125.30 through 125.32, any existing point source subject to this subpart must achieve the following effluent limitations representing the degree of effluent reduction attainable by the application of the best practicable control technology currently available (BPT).

(a) The following limitations establish the quantity or quality of pollutants or pollutant properties, controlled by this paragraph, which may be discharged by an extraction products plant from a point source subject to the provisions of this paragraph after application of the best practicable control technology currently available:

(1) The allowable discharge for the pollutant parameters BOD5 and COD shall be expressed in mass per unit time and shall represent the specified wastewater treatment efficiency in

terms of a residual discharge associated with an influent to the wastewater treatment plant corresponding to the maximum production period for a given pharmaceutical plant as defined in paragraph (a)(4) of this section.

(2) The allowable effluent discharge limitation for the daily average mass of BOD*5* in any calendar month shall specifically reflect not less than 90 percent reduction in the long term daily average raw waste content of BOD*5* multiplied by a variability factor of 3.0. However, a plant shall not be required to attain a maximum 30 day average BOD*5* effluent limitation of less than the equivalent of 45 mg/l.

(3) The allowable effluent discharge limitation for the daily average mass of COD in any calendar month shall specifically reflect not less than 74 percent reduction in the long term daily average raw waste content of COD multiplied by a variability factor of 2.2. However, a plant shall not be required to attain a maximum 30 day average COD effluent limitation of less than the equivalent of 220 mg/l.

(4) The long term daily average raw waste load for the pollutants BOD*5* and COD is defined as the average daily mass of each pollutant discharged in the influent to the wastewater treatment system over a 12 consecutive month period within the most recent 36 months, which shall include the greatest production effort.

(5) To assure equity in regulating discharges from the point sources covered by this subpart of the point source category, calculation of raw waste loads of BOD*5* and COD for the purpose of determining NPDES permit limitations (i.e., the base numbers to which the percent reductions are applied) shall exclude any waste load associated with solvents in those raw waste loads, except that residual amounts of solvents remaining after the practice of recovery and/or separate disposal or reuse may be included in the calculation of the raw waste loads. Those practices of removal, disposal, or reuse include recovery of solvents from waste streams and incineration of concentrated solvent waste streams (including tar still bottoms). This regulation does not prohibit inclusion of such wastes in the raw waste loads in fact, nor does it mandate any specific practice, but rather describes the rationale for determining the permit conditions. These limits may be achieved by any one of several or a combination thereof of programs and practices.

(6) The allowable effluent discharge limitation for the daily mass of TSS in any calendar month shall be 1.7 times the BOD*5* limitation determined in paragraph (a)(2) of this section.

(7) The pH shall be within the range of 6.0–9.0 standard units.

(8) For those plants using or generating cyanide in the manufacturing process, the allowable effluent discharge for cyanide is shown below.

(i)

Pollutant of pollutant property	BPT effluent limitations	
	Maximum for any 1 day	Average of daily values for 30 consecutive days
	Milligrams per liter (mg/l)	
Total cyanide	33.5	9.4

(ii) If all cyanide-containing waste streams are diverted to a cyanide destruction unit and the effluent from the cyanide destruction unit is discharged to a biological treatment system, self-monitoring must be conducted after cyanide treatment and before dilution with other streams. Alternatively, self-monitoring may be conducted at the final effluent discharge point, if the daily maximum cyanide limitation is multiplied by 0.18, the maximum 30 day average cyanide limitation is multiplied by 0.35, and both limitations are adjusted based on the dilution ratio of the cyanide-contaminated waste stream flow to the total process wastewater discharge flow. However, if all cyanide-containing waste streams are not treated in a cyanide destruction unit or if the effluent from the cyanide destruction unit is not discharged to a biological treatment system, self-monitoring must be conducted at the final effluent discharge point and the daily maximum cyanide limitation must be multiplied by 0.18, the maximum 30 day average cyanide limitation must be multiplied by 0.35, and both limitations must be adjusted based on the dilution ratio of the cyanide-contaminated waste stream flow to the total process wastewater discharge flow. Permittees not using or generating cyanide must certify to the permit-issuing authority that they are not using or generating this compound.

(b) Dilution to meet the above effluent limitations may not be practiced.

§ 439.23 Effluent limitations representing the degree of effluent reduction attainable by the application of the best conventional pollutant control technology (BCT). [Reserved]

§ 439.24 Effluent limitations representing the degree of effluent reduction attainable by the application of the best available technology economically achievable (BAT).

(a) Except as provided in 40 CFR 125.30 through 125.32, any existing point source subject to this subpart where cyanide is used or generated in the manufacturing process must achieve the following effluent limitations representing the degree of effluent reduction attainable by the application of the best available technology economically achievable (BAT).

(1)

Pollutant or pollutant property	BAT effluent limitations	
	Maximum for any 1 day	Average of daily values for 30 consecutive days
	Milligrams per liter (mg/l)	
Total Cyanide	33.5	9.4
COD	(1)	(1)

[1] Reserved.

(2) If all cyanide-containing waste streams are diverted to a cyanide destruction unit and the effluent from the cyanide destruction unit is discharged to a biological treatment system, self-monitoring must be conducted after cyanide treatment and before dilution with other streams. Alternatively, self-monitoring may be conducted at the final effluent discharge point, if the daily maximum cyanide limitation is multiplied by 0.18, the maximum 30 day average cyanide limitation is multiplied by 0.35, and both limitations are adjusted based on the dilution ratio of the cyanide-contaminated waste stream flow to the total process wastewater discharge flow. However, if all cyanide-containing waste streams are not treated in a cyanide destruction unit or if the effluent from the cyanide destruction unit is not discharged to a biological treatment system, self-monitoring must be conducted at the final effluent discharge point and the daily maximum cyanide limitation must be multiplied by 0.18, the maximum 30 day average cyanide limitations must be multiplied by 0.35, and both limitations must be adjusted based on the dilution ratio of the cyanide-contaminated waste stream

flow to the total process wastewater discharge flow. Permittees not using or generating cyanide must certify to the permit-issuing authority that they are not using or generating this compound.

(b) Dilution in order to meet the above effluent limitations may not be practiced.

§ 439.25 New source performance standards (NSPS).

(a) The following standards of performance establish the quantity or quality of pollutants or pollutant properties, controlled by this section, which may be discharged by a new source subject to the provisions of this subpart.

(1)

Pollutant or pollutant property	NSPS	
	Maximum for any 1 day	Average of daily values for 30 consecutive days
	Milligrams per liter (mg/l)	
Total cyanide	33.5	9.4
BOD5	(1)	(1)
TSS	(1)	(1)
COD	(1)	(1)
pH	(2)	(2)

[1] Reserved.
[2] Within the range of 6.0 to 9.0 at all times.

(2) If all cyanide-containing waste streams are diverted to a cyanide destruction unit and the effluent from the cyanide destruction unit is discharged to a biological treatment system, self-monitoring must be conducted after cyanide treatment and before dilution with other streams. Alternatively, self-monitoring may be conducted at the final effluent discharge point, if the daily maximum cyanide standard is multiplied by 0.18, the maximum 30 day average cyanide standard is multiplied by 0.35, and both standards are adjusted based on the dilution ratio of the cyanide-contaminated waste stream flow to the total process wastewater discharge flow. However, if all cyanide-containing waste streams are not treated in a cyanide destruction unit or if the effluent from the cyanide destruction unit is not discharged to a biological treatment system, self-monitoring must be conducted at the final effluent discharge point and the daily maximum cyanide standard must be multiplied by 0.18, the maximum 30 day average cyanide standard must be multiplied by 0.35, and both standards must be adjusted based on the dilution ratio of the cyanide-contaminated waste stream flow to the total process wastewater discharge flow. Only facilities where cyanide is used or generated in the manufacturing process are subject to cyanide standards. Permittees not using or generating cyanide must certify to the permit-issuing authority that they are not using or generating this compound.

(b) Dilution in order to meet the above standards may not be practiced.

§ 439.26 Pretreatment standards for existing sources (PSES).

(a) Except as provided in 40 CFR 403.7 and 403.13, any existing source subject to this subpart that introduces pollutants into a publicly owned treatment works must comply with 40 CFR Part 403 and by October 27, 1986, where cyanide is used or generated in the manufacturing process, must achieve the following pretreatment standards for existing sources (PSES).

(1)

Pollutant or pollutant property	PSES	
	Maximum for any 1 day	Average of daily values for 30 consecutive days
	Milligrams per liter (mg/l)	
Total Cyanide	33.5	9.4

(2) If all cyanide-containing waste streams are diverted to a cyanide destruction unit, self-monitoring for cyanide must be conducted after cyanide treatment and before dilution with other streams. Alternatively, self-monitoring may be conducted at the final effluent discharge point, if the cyanide standard is adjusted based on the dilution ratio of contaminated waste stream flow to the total process wastewater discharge flow. However, if all cyanide-containing waste streams are not treated, self-monitoring must be conducted at the final effluent discharge point and the cyanide standard must be adjusted based on the dilution ratio of contaminated waste stream flow to the total process wastewater discharge flow. Indirect dischargers not using or generating cyanide must certify to the publicly owned treatment works that they are not using or generating this compound.

(b) Dilution in order to meet the above standards may not be practiced.

§ 439.27 Pretreatment standards for new sources (PSNS).

(a) Except as provided in 40 CFR 403.7, any new source subject to this subpart that introduces pollutants into a publicly owned treatment works must comply with 40 CFR Part 403 and where cyanide is used or generated in the manufacturing process, must achieve the following pretreatment standards for new sources (PSNS).

(1)

Pollutant or pollutant property	PSES	
	Maximum for any 1 day	Average of daily values for 30 consecutive days
	Milligrams per liter (mg/l)	
Total Cyanide	33.5	9.4

(2) If all cyanide-containing waste streams are diverted to a cyanide destruction unit, self-monitoring for cyanide must be conducted after cyanide treatment and before dilution with other streams. Alternatively, self-monitoring may be conducted at the final effluent discharge point, if the cyanide standard is adjusted based on the dilution ratio of contaminated waste stream flow to the total process wastewater discharge flow. However, if all cyanide-containing waste streams are not treated, self-monitoring must be conducted at the final effluent discharge point and the cyanide standard must be adjusted based on the dilution ratio of contaminated waste stream flow to the total process wastewater discharge flow. Indirect dischargers not using or generating cyanide must certify to the publicly owned treatment works that they are not using or generating this compound.

(b) Dilution in order to meet the above standards may not be practiced.

Subpart C—Chemical Synthesis Products Subcategory

§ 439.30 Applicability; description of the chemical synthesis products subcategory.

The provisions of this subpart are applicable to discharges resulting from the manufacture of pharmaceuticals by chemical synthesis.

§ 439.31 Specialized definitions.

For the purpose of this subpart:

(a) Except as provided below, the general definitions, abbreviations, and methods of analysis set forth in 40 CFR 401 and 439.01 of this chapter shall apply to this subpart.

(b) The term "product" shall mean pharmaceutical products derived from chemical synthesis processes.

§ 439.32 Effluent limitations representing the degree of effluent reduction attainable by the application of the best practicable control technology currently available (BPT).

Except as provided in 40 CFR 125.30 through 125.32, any existing point source subject to this subpart must achieve the following effluent limitations representing the degree of effluent reduction attainable by the application

of the best practicable control technology currently available (BPT).

(a) The following limitations establish the quantity or quality of pollutants or pollutant properties, controlled by this paragraph, which may be discharged by a chemical synthesis plant from a point source subject to the provisions of this paragraph after application of the best practicable control technology currently available:

(1) The allowable discharge for the pollutant parameters BOD*5* and COD shall be expressed in mass per unit time and shall represent the specified wastewater treatment efficiency in terms of a residual discharge associated with an influent to the wastewater treatment plant corresponding to the maximum production period for a given pharmaceutical plant as defined in paragraph (a)(4) of this section.

(2) The allowable effluent discharge limitation for the daily average mass of BOD*5* in any calendar month shall specifically reflect not less than 90 percent reduction in the long term daily average raw waste content of BOD*5* multiplied by a variability factor of 3.0.

(3) The allowable effluent discharge limitation for the daily average mass of COD in any calendar month shall specifically reflect not less than 74 percent reduction in the long term daily average raw waste content of COD multiplied by a variability factor of 2.2.

(4) The long term daily average raw waste load for the pollutant parameters BOD*5* and COD is defined as the average daily mass of each pollutant discharged in the influent to the wastewater treatment system over a 12 consecutive month period within the most recent 36 months, which shall include the greatest production effort.

(5) To assure equity in regulating discharges from the point sources covered by this subpart of the point source category, calculation of raw waste loads of BOD*5* and COD for the purpose of determining NPDES permit limitations (i.e., the base numbers to which the percent reductions are applied) shall exclude any waste load associated with solvents in those raw waste loads, except that residual amounts of solvents remaining after the practice of recovery and/or separate disposal or reuse may be included in the calculation of the raw waste loads. These practices of removal, disposal, or reuse include recovery of solvents from waste streams and incineration of concentrated solvent waste streams (including tar still bottoms). This regulation does not prohibit inclusion of such wastes in the raw waste loads in fact, nor does it mandate any specific practice, but rather describes the rationale for determining the permit conditions. These limits may be achieved by any one of several or a combination thereof of programs and practices.

(6) The pH shall be within the range of 6.0 to 9.0 standard units.

(7) The allowable effluent discharge limitation for the daily average mass of TSS in any calendar month shall be 1.7 times the BOD*5* limitation determined in paragraph (a)(2) of this section.

(8) For those plants using or generating cyanide in the manufacturing process, the allowable effluent discharge for cyanide is shown below.

(i)

Pollutant or pollutant property	BAT effluent limitations	
	Maximum for any 1 day	Average of daily values for 30 consecutive days
	Milligrams per liter (mg/l)	
Total cyanide	33.5	9.4

(ii) If all cyanide-containing waste streams are diverted to a cyanide destruction unit and the effluent from the cyanide destruction unit is discharged to a biological treatment system, self-monitoring must be conducted after cyanide treatment and before dilution with other streams. Alternatively, self-monitoring may be conducted at the final effluent discharge point, if the daily maximum cyanide limitation is multiplied by 0.18, the maximum 30 day average cyanide limitation is multiplied by 0.35, and both limitations are adjusted based on the dilution ratio of the cyanide-contaminated waste stream flow to the total process wastewater discharge flow. However, if all cyanide-containing waste streams are not treated in a cyanide destruction unit or if the effluent from the cyanide destruction unit is not discharged to a biological treatment system, self-monitoring must be conducted at the final effluent discharge point and the daily maximum cyanide limitation must be multiplied by 0.18, the maximum 30 day average cyanide limitation must be multiplied by 0.35, and both limitations must be adjusted based on the dilution ratio of the cyanide-contaminated waste stream flow to the total process wastewater discharge flow. Permittees not using or generating cyanide must certify to the permit-issuing authority that they are not using or generating this compound.

(b) Dilution to meet the above effluent limitations may not be practiced.

§ 439.33 Effluent limitations representing the degree of effluent reduction attainable by the application of the best conventional pollutant control technology (BCT). [Reserved]

§ 439.34 Effluent limitations representing the degree of effluent reduction attainable by the application of the best available technology economically achievable (BAT).

(a) Except as provided in 40 CFR 125.30 through 125.32, any existing point source subject to this subpart where cyanide is used or generated in the manufacturing process must achieve the following effluent limitations representing the degree of effluent reduction attainable by the application of the best available technology economically achievable (BAT).

(1)

Pollutant or pollutant property	BAT effluent limitations	
	Maximum for any 1 day	Average of daily values for 30 consecutive days
	Milligrams per liter (mg/l)	
Total cyanide	33.5	9.4
COD	(1)	(1)

[1] Reserved.

(2) If all cyanide-containing waste streams are diverted to a cyanide destruction unit and the effluent from the cyanide destruction unit is discharged to a biological treatment system, self-monitoring must be conducted after cyanide treatment and before dilution with other streams. Alternatively, self-monitoring may be conducted at the final effluent discharge point, if the daily maximum cyanide limitation is multiplied by 0.18, the maximum 30 day average cyanide limitation is multiplied by 0.35, and both limitations are adjusted based on the dilution ratio of the cyanide-contaminated waste stream flow to the total process wastewater discharge flow. However, if all cyanide-containing waste streams are not treated in a cyanide destruction unit is not discharged to a biological treatment system, self-monitoring must be conducted at the final effluent discharge point and the daily maximum cyanide limitation must be multiplied by 0.18, the maximum 30 day average cyanide limitation must be multiplied by 0.35, and both limitations must be adjusted based on the dilution ratio of the cyanide-contaminated waste stream flow to the total process wastewater discharge flow. Permittees not using or generating cyanide must certify to the permit-issuing authority that they are not using or generating this compound

(b) Dilution in order to meet the above effluent limitations may not be practiced.

§ 439.35 New source performance standards (NSPS).

(a) The following standards of performance establish the quantity or quality of pollutants or pollutant properties, controlled by this section, which may be discharged by a new source subject to the provisions of this subpart.

(1)

Pollutant or pollutant property	NSPS	
	Maximum for any 1 day	Average of daily values for 30 consecutive days
	Milligrams per liter (mg/l)	
Total cyanide	33.5	9.4
BOD[5]	(1)	(1)
TSS	(1)	(1)
COD	(1)	(1)
pH	(2)	(2)

[1] Reserved.
[2] Within the range of 6.0 to 9.0 at all times.

(2) If all cyanide-containing waste streams are diverted to a cyanide destruction unit and the effluent from the cyanide destruction unit is discharged to a biological treatment system, self-monitoring must be conducted after cyanide treatment and before dilution with other streams. Alternatively, self-monitoring may be conducted at the final effluent discharge point, if the daily maximum cyanide standard is multiplied by 0.18, the maximum 30 day average cyanide standard is multiplied by 0.35, and both standards are adjusted based on the dilution ratio of the cyanide-contaminated waste stream flow to the total process wastewater discharge flow. However, if all cyanide-containing waste streams are not treated in a cyanide destruction unit or if the effluent from the cyanide destruction unit is not discharged to a biological treatment system, self-monitoring must be conducted at the final effluent discharge point and the daily maximum cyanide standard must be multiplied by 0.18, the maximum 30 day average cyanide standard must be multiplied by 0.35, and both standards must be adjusted based on the dilution ratio of the cyanide-contaminated waste stream flow to the total process wastewater discharge flow. Only facilities where cyanide is used or generated in the manufacturing process are subject to cyanide standards. Permittees not using or generating cyanide must certify to the permit-issuing authority that they are not using or generating this compound.

(b) Dilution in order to meet the above standards may not be practiced.

§ 439.36 Pretreatment standards for existing sources (PSES).

(a) Except as provided in 40 CFR 403.7 and 403.13, any existing source subject to this subpart that introduces pollutants into a publicly owned treatment works must comply with 40 CFR Part 403 and by October 27, 1986, where cyanide is used or generated in the manufacturing process, must achieve the following pretreatment standards for existing sources (PSES).

(1)

Pollutant or pollutant property	PSES	
	Maximum for any 1 day	Average of daily values for 30 consecutive days
	Milligrams per liter (mg/l)	
Total Cyanide	33.5	9.4

(2) If all cyanide-containing waste streams are diverted to a cyanide destruction unit, self-monitoring for cyanide must be conducted after cyanide treatment and before dilution with other streams. Alternatively, self-monitoring may be conducted at the final effluent discharge point, if the cyanide standard is adjusted based on the dilution ratio of contaminated waste stream flow to the total process wastewater discharge flow. However, if all cyanide-containing waste streams are not treated, self-monitoring must be conducted at the final effluent discharge point and the cyanide standard must be adjusted based on the dilution ratio of contaminated waste stream flow to the total process wastewater discharge flow. Indirect dischargers not using or generating cyanide must certify to the publicly owned treatment works that they are not using or generating this compound.

(b) Dilution in order to meet the above standards may not be practiced.

§ 439.37 Pretreatment standards for new sources (PSNS).

(a) Except as provided in 40 CFR 403.7, any new source subject to this subpart that introduces pollutants into a publicly owned treatment works must comply with 40 CFR Part 403 and where cyanide is used or generated in the manufacturing process, must achieve the following pretreatment standards for new sources (PSNS).

(1)

Pollutant or pollutant property	PSNS	
	Maximum for any 1 day	Average of daily values for 30 consecutive days
	Milligrams per liter (mg/l)	
Total Cyanide	33.5	9.4

(2) If all cyanide-containing waste streams are diverted to a cyanide destruction unit, self-monitoring for cyanide must be conducted after cyanide treatment and before dilution with other streams. Alternatively, self-monitoring may be conducted at the final effluent discharge point, if the cyanide standard is adjusted based on the dilution ratio of contaminated waste stream flow to the total process wastewater discharge flow. However, if all cyanide-containing streams are not treated, self-monitoring must be conducted at the final effluent discharge point and the cyanide standard must be adjusted based on the dilution ratio of contaminated waste stream flow to the total process wastewater discharge flow. Indirect dischargers not using or generating cyanide must certify to the publicly owned treatment works that they are not using or generating this compound.

(b) Dilution in order to meet the above standards may not be practiced.

Subpart D—Mixing/Compounding and Formulation Subcategory

§ 439.40 Applicability; description of the mixing/compounding and formulation subcategory.

The provisions of this subpart are applicable to discharges resulting from mixing/compounding and formulaton operations of pharmaceutical products.

§ 439.41 Specialized definitions.

For the purpose of this subpart:

(a) Except as provided below, the general definitions, abbreviations, and methods of analysis set forth in 40 CFR Part 401 and 439.01 of this chapter shall apply to this subpart.

(b) The term "product" shall mean products from plants which blend, mix, compound, and formulate pharmaceutical ingredients. Pharmaceutical preparations for human and veterinary use such as ampules, tablets, capsules, vials, ointments, medicinal powders, solutions, and suspensions are included.

§ 439.42 Effluent limitations representing the degree of effluent reduction attainable by the application of the best practicable control technology currently available (BPT).

Except as provided in 40 CFR 125.30 through 125.32, any existing point source subject to this subpart must achieve the following effluent limitations representing the degree of effluent reduction attainable by the application of the best practicable control technology currently available (BPT).

(a) The following limitations establish the quantity or quality of pollutants or pollutant properties, controlled by this paragraph, which may be discharged by a mixing/compounding and formulation plant from a point source subject to the provisions of this paragraph after application of the best practicable control technology currently available:

(1) The allowable discharge for the pollutant parameters BOD*5* and COD shall be expressed in mass per unit time and shall represent the specified wastewater treatment efficiency in terms of a residual discharge associated with an influent to the wastewater treatment plant corresponding to the maximum production period for a given pharmaceutical plant as defined in paragraph (a)(4) of this section.

(2) The allowable effluent discharge limitation for the daily average mass of BOD*5* in any calendar month shall specifically reflect not less than 90 percent reduction in the long term daily average raw waste content of BOD*5* multiplied by a variability factor 3.0. However, a plant shall not be required to attain a maximum 30 day average BOD*5* effluent limitation of less than the equivalent of 45 mg/l.

(3) The allowable effluent discharge limitation for the daily average mass of COD in any calendar month shall specifically reflect not less than 74 percent reduction in the long term daily average raw waste content of COD multiplied by a variability factor of 2.2. However, a plant shall not be required to attain a maximum 30 day average COD effluent limitation of less than the equivalent of 220 mg/l.

(4) The long term daily average raw waste load for the pollutant parameters BOD*5* and COD is defined as the average daily mass of each pollutant discharged in the influent to the wastewater treatment system over a 12 consecutive month period within the most recent 36 months, which shall include the greatest production effort.

(5) To assure equity in regulating discharges from the point sources covered by this subpart of the point source category, calculation of raw waste loads of BOD*5* and COD for the purpose of determining NPDES per limitations (i.e., the base numbers to which the percent reductions are applied) shall exclude any waste load associated with solvents in those raw waste loads except that residual amounts of solvents remaining after the practice of recovery and/or separate disposal or reuse may be included in the calculation of the raw waste loads. These practices of removal, disposal, or reuse include recovery of solvents from waste streams and incineration of concentrated solvent waste streams (including tar still bottoms). This regulation does not prohibit inclusion of such wastes in the raw waste loads in fact, nor does it mandate any specific practice, but rather describes the rationale for determining the permit conditions. These limits may be achieved by any one of several or a combination thereof of programs and practices.

(6) The allowable effluent discharge limitation for the daily average mass of TSS in any calendar month shall be 1.7 times the BOD*5* limitation determined in (2) above.

(7) The pH shall be within the range of 6.0–9.0 standard units.

(8) For those plants using or generating cyanide in the manufacturing process, the allowable effluent discharge for cyanide is shown below.

(i) See table below:

Pollutant or pollutant property	BPT effluent limitations	
	Maximum for any 1 day	Average of daily values for 30 consecutive days
	Milligrams per liter (mg/l)	
Total cyanide	33.5	9.4

(ii) If all cyanide-containing waste streams are diverted to a cyanide destruction unit and the effluent from the cyanide destruction unit is discharged to a biological treatment system, self-monitoring must be conducted after cyanide treatment and before dilution with other streams. Alternatively, self-monitoring may be conducted at the final effluent discharge point, if the daily maximum cyanide limitation is multiplied by 0.18, the maximum 30 day average cyanide limitation is multiplied by 0.35, and both limitations are adjusted based on the dilution ratio of the cyanide-contaminated waste stream flow to the total process wastewater discharge flow. However, if all cyanide-containing waste streams are not treated in a cyanide destruction unit or if the effluent from the cyanide destruction unit is not discharged to a biological treatment system, self-monitoring must be conducted at the final effluent discharge point and the daily maximum cyanide limitation must be multiplied by 0.18, the maximum 30 day average cyanide limitation must be multiplied by 0.35, and both limitations must be adjusted based on the dilution ratio of the cyanide-contaminated waste stream flow to the total process wastewater discharge flow. Permittees not using or generating cyanide must certify to the permit-issuing authority that they are not using or generating this compound.

(b) Dilution to meet the above effluent limitations may not be practiced.

§ 439.43 Effluent limitations representing the degree of effluent reduction attainable by the application of the best conventional pollutant control technology (BCT). [Reserved]

§ 439.44 Effluent limitations representing the degree of effluent reduction attainable by the application of the best available technology economically achievable (BAT).

(a) Except as provided in 40 CFR 125.30 through 125.32, any existing point source subject to this subpart where cyanide is used or generated in the manufacturing process must achieve the following effluent limitations representing the degree of effluent reduction attainable by the application of the best available technology economically achievable (BAT).

(1)

Pollutant or pollutant property	BAT effluent limitations	
	Maximum for any 1 day	Average of daily values for 30 consecutive days
	Milligrams per liter (mg/l)	
Total cyanide	33.5	9.4
COD	(1)	(1)

(2) If all cyanide-containing waste streams are diverted to a cyanide destruction unit and the effluent from the cyanide destruction unit is discharged to a biological treatment system, self-monitoring must be conducted after cyanide treatment and before dilution with other streams. Alternatively, self-monitoring may be conducted at the final effluent discharge point, if the daily maximum cyanide limitation is multiplied by 0.18, the maximum 30 day average cyanide limitation is multiplied by 0.35, and both limitations are adjusted based on the dilution ratio of the cyanide-contaminated waste stream flow to the total process wastewater discharge flow. However, if all cyanide-containing waste streams are not treated in a

cyanide destruction unit or if the effluent from the cyanide destruction unit is not discharged to a biological treatment system, self-monitoring must be conducted at the final effluent discharge point and the daily maximum cyanide limitation must be multiplied by 0.18, the maximum 30 day average cyanide limitation must be multiplied by 0.35, and both limitations must be adjusted based on the dilution ratio of the cyanide-contaminated waste stream flow to the total process wastewater discharge flow. Permittees not using or generating cyanide must certify to the permit-issuing authority that they are not using or generating this compound.

(b) Dilution in order to meet the above effluent limitations may not be practiced.

§ 439.45 New source performance standards (NSPS).

(a) The following standards of performance establish the quantity or quality of pollutants or pollutant properties, controlled by this section, which may be discharged by a new source subject to the provisions of this subpart.

(1)

Pollutant or pollutant property	NSPS	
	Maximum for any 1 day	Average of daily values for 30 consecutive days
	Milligrams per liter (mg/l)	
Total cyanide	33.5	9.4
BOD5	(1)	(1)
TSS	(1)	(1)
COD	(1)	(1)
pH	(2)	(2)

[1] Reserved.
[2] Within the range of 6.0 to 9.0 at all times.

(2) If all cyanide-containing waste streams are diverted to a cyanide destruction unit and the effluent from the cyanide destruction unit is discharged to a biological treatment system, self-monitoring must be conducted after cyanide treatment and before dilution with other streams. Alternatively, self-monitoring may be conducted at the final effluent discharge point, if the daily maximum cyanide standard is multiplied by 0.18, the maximum 30 day average cyanide standard is multiplied by 0.35, and both standards are adjusted based on the dilution ratio of the cyanide-contaminated waste stream flow to the total process wastewater discharge flow. However, if all cyanide-containing waste streams are not treated in a cyanide destruction unit or if the effluent from the cyanide destruction unit is not discharged to a biological treatment system, self-monitoring must be conducted at the final effluent discharge point and the daily maximum cyanide standard must be multiplied by 0.18, the maximum 30 day average cyanide standard must be multiplied by 0.35, and both standards must be adjusted based on the dilution ratio of the cyanide-contaminated waste stream flow to the total process wastewater discharge flow. Only facilities where cyanide is used or generated in the manufacturing process are subject to cyanide standards. Permittees not using or generating cyanide must certify to the permit-issuing authority that they are not using or generating this compound.

(b) Dilution in order to meet the above standards may not be practiced.

§ 439.46 Pretreatment standards for existing sources (PSES).

(a) Except as provided in 40 CFR 403.7 and 403.13, any existing source subject to this subpart that introduces pollutants into a publicly owned treatment works must comply with 40 CFR Part 403 and by October 27, 1986, where cyanide is used or generated in the manufacturing process, must achieve the following pretreatment standards for existing sources (PSES).

(1)

Pollutant or pollutant property	PSES	
	Maximum for any 1 day	Average of daily values for 30 consecutive days
	Milligrams per liter (mg/l)	
Total cyanide	33.5	9.4

(2) If all cyanide-containing waste streams are diverted to a cyanide destruction unit, self-monitoring for cyanide must be conducted after cyanide treatment and before dilution with other streams. Alternatively, self-monitoring may be conducted at the final effluent discharge point, if the cyanide standard is adjusted based on the dilution ratio of contaminated waste stream flow to the total process wastewater discharge flow. However, if all cyanide-containing waste streams are not treated, self-monitoring must be conducted at the final effluent discharge point and the cyanide standard must be adjusted based on the dilution ratio of contaminated waste stream flow to the total process wastewater discharge flow. Indirect dischargers not using or generating cyanide must certify to the publicly owned treatment works that they are not using or generating this compound.

(b) Dilution in order to meet the above standards may not be practiced.

§ 439.47 Pretreatment standards for new sources (PSNS).

(a) Except as provided in 40 CFR 403.7 any new source subject to this subpart that introduces pollutants into a publicly owned treatment works must comply with 40 CFR Part 403 and where cyanide is used or generated in the manufacturing process, must achieve the following pretreatment standards for new sources (PSNS).

(1)

Pollutant or pollutant property	PSNS	
	Maximum for any 1 day	Average of daily values for 30 consecutive days
	Milligrams per liter (mg/l)	
Total cyanide	33.5	9.4

(2) If all cyanide-containing waste streams are diverted to a cyanide destruction unit, self-monitoring for cyanide must be conducted after cyanide treatment and before dilution with other streams. Alternatively, self-monitoring may be conducted at the final effluent discharge point, if the cyanide standard is adjusted based on the dilution ratio of contaminated waste stream flow to the total process wastewater discharge flow. However, if all cyanide-containing waste streams are not treated, self-monitoring must be conducted at the final effluent discharge point and the cyanide standard must be adjusted based on the dilution ratio of contaminated waste stream flow to the total process wastewater discharge flow. Indirect dischargers not using or generating cyanide must certify to the publicly owned treatment works that they are not using or generating this compound.

(b) Dilution in order to meet the above standards may not be practiced.

Subpart E—Research Subcategory

§ 439.50 Applicability; description of the research subcategory.

The provisions of this subpart are applicable to discharges resulting from pharmaceutical research.

§ 439.51 Specialized definitions.

For the purpose of this subpart:

(a) Except as provided below, the general definitions, abbreviations, and methods of analysis set forth in in 40 CFR Part 401 and 439.01 shall apply to this subpart.

(b) The term "product" shall mean products or services resulting from pharmaceutical research, which includes

microbiological, biological, and chemical operations.

§ 439.52 Effluent limitations representing the degree of effluent reduction attainable by the application of the best practicable control technology currently available (BPT).

Except as provided in 40 CFR 125.30 through 125.32, any existing point source subject to this subpart must achieve the following effluent limitations representing the degree of effluent reduction attainable by the application of the best practicable control technology currently available (BPT).

(a) The following limitations establish the quantity or quality of pollutants or pollutant properties, controlled by this paragraph, which may be discharged by a pharmaceutical research operation from a point source subject to the provisions of this paragraph after application of the best practicable control technology currently available:

(1) The allowable discharge for the pollutant parameters BOD*5* and COD shall be expressed in mass per unit time and shall represent the specified wastewater treatment efficiency in terms of a residual discharge associated with an influent to the wastewater treatment plant corresponding to the maximum production period for a given pharmaceutical plant as defined in paragraph (a)(4) of this section.

(2) The allowable effluent discharge limitation for the daily average mass of BOD*5* in any calendar month shall specifically reflect not less than 90 percent reduction in the long term daily average raw waste content of BOD*5* multiplied by a variability factor of 3.0. However, a plant shall not be required to attain a maximum 30 day average BOD*5* effluent limitation of less than the equivalent of 45 mg/l.

(3) The allowable effluent discharge limitation for the daily average mass of COD in any calendar month shall specifically reflect not less than 74 percent reduction in the long term daily average raw waste content of COD multiplied by a variability factor of 2.2. However, a plant shall not be required to attain a maximum 30 day average COD effluent limitation of less than the equivalent of 220 mg/l.

(4) The long term daily average raw waste load for the pollutant parameters BOD*5* and COD is defined as the average daily mass of each pollutant influent to the wastewater treatment system over a 12 consecutive month period within the most recent 36 months, which shall include the greatest production effort.

(5) To assure equity in regulation discharges from the point sources covered by this subpart of the point source category, calculation of raw waste loads of BOD*5* and COD for the purpose of determining NPDES permit limitations (i.e., the base numbers to which the percent reductions are applied) shall exclude any waste load associated with solvents in those raw waste loads, except that residual amounts of solvents remaining after the practice of recovery and/or separate disposal or reuse may be included in the calculation of the raw waste loads. These practices of removal, disposal, or reuse include recovery of solvents from waste streams and incineration of concentrated solvent waste streams (including tar still bottoms). This regulation does not prohibit inclusion of such wastes in the raw waste loads in fact, nor does it mandate any specific practice, but rather describes the rationale for determining the permit conditions. These limits may be achieved by any one of several or a combination thereof of programs and practices.

(6) The allowable effluent discharge limitation for the daily average mass of TSS in any calendar month shall be 1.7 times the BOD*5* limitation determined in paragraph (a)(2) of this section.

(7) The pH shall be within the range of 6.0–9.0 standard units.

(b) Dilution to meet the above effluent limitations may not be practiced.

§ 439.53 Effluent limitations representing the degree of effluent reduction attainable by the application of the best conventional pollutant control technology (BCT). [Reserved]

§ 439.54 Effluent limitations representing the degree of effluent reduction attainable by the application of the best available technology economically achievable (BAT). [Reserved]

§ 439.55 New source performance standards (NSPS). [Reserved]

§ 439.56 Pretreatment standards for existing sources (PSES). [Reserved]

§ 439.57 Pretreatment standards for new sources (PSNS). [Reserved]

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