Subpart AJ—Talc, Steatite, Soapstone and Pyrophyllite Subcategory [Reserved]

Subpart AK—Garnet Subcategory [Reserved]

Subpart AL—Graphite Subcategory

§ 436.380 Applicability; description of the graphite subcategory.

The provisions of this subpart are applicable to the mining and processing of naturally occurring graphite.

§ 436.381 Specialized definitions.

For the purpose of this subpart:

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

(b) The term ''mine drainage'' shall mean any water drained, pumped or siphoned from a mine.

§ 436.382 Effluent limitations guidelines representing the degree of effluent reduction attainable by the application of the best practicable control technology currently available.

(a) Except as provided in §§ 125.30 through 125.32, and subject to the provisions of paragraph (b) of this section, any existing point source subject to this subpart shall achieve the following effluent limitations representing the degree of effluent reduction attainable by the application of the best practicable control technology currently available (BPT):

Effluent characteristic	Effluent limitations	
	Maximum for any 1 day	Average of daily values for 30 consecutive days shall not exceed—
TSS	20 mg/l	10 mg/l.
Total Fe	2 mg/l	1 mg/l.
pH	(1)	(1)

[1] Within the range 6.0 to 9.0.

(b) Only that volume of water resulting from precipitation that exceeds the maximum safe surge capacity of a process waste water impoundment may be discharged from that impoundment. The height difference between the maximum safe surge capacity level and the normal operating level must be greater than the inches of rain representing the 10-year, 24-hour rainfall event as established by the National Climatic Center, National Oceanic and Atmospheric Administration for the locality in which such impoundment is located.

[40 FR 48657, Oct. 16, 1975, as amended at 60 FR 33969, June 29, 1995; 60 FR 35796, July 11, 1995]

PART 439—PHARMACEUTICAL MANUFACTURING POINT SOURCE CATEGORY

GENERAL PROVISIONS

Subpart C—Chemical Synthesis Products Subcategory

Subpart D—Mixing/Compounding and Formulation Subcategory

Subpart E—Research Subcategory

AUTHORITY: Secs. 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.

SOURCE: 48 FR 49821, Oct. 27, 1983, unless otherwise noted.

GENERAL PROVISIONS

§ 439.0 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.

[48 FR 49821, Oct. 27, 1983; 48 FR 50322, Nov. 1, 1983]

§ 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 BOD5 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 BOD5 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 loads 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) 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.

(Information collection requirements in paragraph (a) were approved by the Office of Management and Budget under control number 2040–0033)

[48 FR 49821, Oct. 27, 1983; 49 FR 1190, Jan. 10, 1984, as amended at 50 FR 4515, Jan. 31, 1985]

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

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 application of the best conventional pollutant control technology (BCT): The limitations shall be the same as those specified for conventional pollutants (which are defined in §401.16) in §439.12 of this subpart for best practicable control technology currently available (BPT).

[51 FR 45098, Dec. 16, 1986]

§ 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.

(Information collection requirements in paragraph (a) were approved by the Office of Management and Budget under control number 2040–0033)

[48 FR 49821, Oct. 27, 1983, as amended at 50 FR 4515, Jan. 31, 1985]

§ 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
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.

(Information collection requirements in paragraph (a) were approved by the Office of Management and Budget under control number 2040–0033)

[48 FR 49821, Oct. 27, 1983, as amended at 50 FR 18486, May 1, 1985]

§ 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.

(Information collection requirements in paragraph (a) were approved by the Office of Management and Budget under control number 2040–0033)

[48 FR 49821, Oct. 27, 1983, as amended at 50 FR 4515, Jan. 31, 1985]

§ 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.

(Information collection requirements in paragraph (a) were approved by the Office of Management and Budget under control number 2040–0033)

[48 FR 49821, Oct. 27, 1983, as amended at 50 FR 4515, Jan. 31, 1985]

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 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 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.

(Information collection requirements in paragraph (a) were approved by the Office of Management and Budget under control number 2040–0033)

[48 FR 49821, Oct. 27, 1983, as amended at 50 FR 4515, Jan. 31, 1985]

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

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 application of the best conventional pollutant control technology (BCT): The limitations shall be the same as those specified for conventional pollutants (which are defined in § 401.16) in § 439.22 of this subpart for best practicable control technology currently available (BPT).

[51 FR 45099, Dec. 16, 1986]

§ 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.

(Information collection requirements in paragraph (a) were approved by the Office of Management and Budget under control number 2040–0033)

[48 FR 49821, Oct. 27, 1983, as amended at 50 FR 4515, Jan. 31, 1985]

§ 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
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.

(Information collection requirements in paragraph (a) were approved by the Office of Management and Budget under control number 2040–0033)

[48 FR 49821, Oct. 27, 1983, as amended at 50 FR 4515, Jan. 31, 1985]

§ 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.

(Information collection requirements in paragraph (a) were approved by the Office of Management and Budget under control number 2040–0033)

[48 FR 49821, Oct. 27, 1983, as amended at 50 FR 4515, Jan. 31, 1985]

§ 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.

(Information collection requirements in paragraph (a) were approved by the Office of Management and Budget under control number 2040–0033)

[48 FR 49821, Oct. 27, 1983, as amended at 50 FR 4515, Jan. 31, 1985]

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 part 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 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 BOD5 in any calendar month shall specifically reflect not less than 90 percent reduction in the long term daily average raw waste content of BOD5 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 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.

(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 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 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 BOD5 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.

(Information collection requirements in paragraph (a) were approved by the Office of Management and Budget under control number 2040–0033)

[48 FR 49821, Oct. 27, 1983, as amended at 50 FR 4515, Jan. 31, 1985]

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

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 application of the best conventional pollutant control technology (BCT): The limitations shall be the same as those specified for conventional pollutants (which are defined in §401.16) in §439.32 of this subpart for best practicable control technology currently available (BPT.

[51 FR 45099, Dec. 16, 1986]

§ 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.

(Information collection requirements in paragraph (a) were approved by the Office of Management and Budget under control number 2040–0033)

[48 FR 49821, Oct. 27, 1983, as amended at 50 FR 4515, Jan. 31, 1985]

§ 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.

(Information collection requirements in paragraph (a) were approved by the Office of Management and Budget under control number 2040–0033)

[48 FR 49821, Oct. 27, 1983, as amended at 50 FR 4515, Jan. 31, 1985]

§ 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.

(Information collection requirements in paragraph (a) were approved by the Office of Management and Budget under control number 2040–0033)

[48 FR 49821, Oct. 27, 1983, as amended at 50 FR 4515, Jan. 31, 1985]

§ 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.

(Information collection requirements in paragraph (a) were approved by the Office of Management and Budget under control number 2040–0033)

[48 FR 49821, Oct. 27, 1983, as amended at 50 FR 4515, Jan. 31, 1985]

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 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 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.

(Information collection requirements in paragraph (a) were approved by the Office of Management and Budget under control number 2040–0033)

[48 FR 49821, Oct. 27, 1983, as amended at 50 FR 4515, Jan. 31, 1985]

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

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 application of the best conventional pollutant control technology (BCT): The limitations shall be the same as those specified for conventional pollutants (which are defined in § 401.16) in § 439.42 of this subpart for best practicable control technology currently available (BPT).

[51 FR 45099, Dec. 16, 1986]

§ 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]

[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.

(Information collection requirements in paragraph (a) were approved by the Office of Management and Budget under control number 2040–0033)

[48 FR 49821, Oct. 27, 1983, as amended at 50 FR 4515, Jan. 31, 1985]

§ 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
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.

(Information collection requirements in paragraph (a) were approved by the Office of Management and Budget under control number 2040–0033)

[48 FR 49821, Oct. 27, 1983, as amended at 50 FR 4515, Jan. 31, 1985]

§ 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.

(Information collection requirements in paragraph (a) were approved by the Office of Management and Budget under control number 2040–0033)

[48 FR 49821, Oct. 27, 1983, as amended at 50 FR 4515, Jan. 31, 1985]

§ 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.

(Information collection requirements in paragraph (a) were approved by the Office of Management and Budget under control number 2040–0033)

[48 FR 49821, Oct. 27, 1983, as amended at 50 FR 4515, Jan. 31, 1985]

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 BOD5 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]

PART 440—ORE MINING AND DRESSING POINT SOURCE CATEGORY

Subpart A—Iron Ore Subcategory

Sec.

Subpart B—Aluminum Ore Subcategory

Subpart C—Uranium, Radium, and Vanadium Ores Subcategory