5. What are the Technological Bases for Effluent Limitations Guidelines and Standards for Subparts A, B, C, and D?

5.1 What are the Model Process Technologies and Wastewater Treatment Systems?

5.1.1 Regulatory Bases of Effluent Limitations Guidelines and Standards Applicable to Direct and Indirect Dischargers

5.1.2 Model Technologies That Form the Bases of Effluent Limitations Guidelines and Standards

6. Where Are Facilities Required to Demonstrate Compliance?

7. What are the Effluent Limitations Guidelines and Standards for Subparts A, B, C, D, and E?

7.1 Direct Dischargers

7.1.1 BPT, BAT and NSPS

7.2 Indirect Dischargers

7.2.1 PSES and PSNS

5. What are the Technological Bases for Effluent Limitations Guidelines and Standards for Subparts A, B, C, and D

EPA established numerical effluent limitations guidelines and pretreatment standards for subparts A, B, C, and D based on model process technologies and wastewater treatment technologies. Although effluent limitations guidelines and standards must be applied in the NPDES permit or pretreatment permit or control mechanism, facilities with operations in subparts A, B, C, and D are not required to use the specific process and/or technologies on which EPA based the effluent limitations guidelines and standards. Facility owners and operators may use any combination of process technologies and in-process or end-of-pipe wastewater treatment technologies to comply with the required limits.

5.1 What are the Model Process Technologies and Wastewater Treatment Systems?

This section outlines the various technology levels and model technologies that form the regulatory bases of the effluent limitations guidelines and standards presented in Section 4.

5.1.1 Regulatory Bases of Effluent Limitations Guidelines and Standards Applicable to Direct and Indirect Dischargers

BPT

Effluent limitations guidelines based on BPT apply to direct discharges and are generally based on the average of the best existing performance, in terms of treated effluent discharged, by facilities in a subcategory. BPT focuses on end-of-pipe treatment technology and such process changes and internal controls that are common industry practice.

BAT

Effluent limitations guidelines based on BAT represent the best existing economically achievable performance of plants in the industrial subcategory. The CWA establishes BAT as the principal national means of controlling the direct discharge of priority pollutants and nonconventional pollutants to waters of the United States.

BCT

The CWA requires EPA to identify effluent reduction levels for conventional pollutants associated with BCT technology for discharges from existing industrial point sources. BCT is not an additional limitation, but replaces BAT for control of conventional pollutants. In addition to other factors, the CWA requires that EPA establish BCT limitations after consideration of a two part ‘‘cost reasonableness’’ test.

NSPS

The basis for NSPS under Section 306 of the CWA is the best available demonstrated technology. New source industrial dischargers have the opportunity to design and install the best and most efficient manufacturing processes and wastewater treatment systems at new plants. Accordingly, Congress directed EPA to consider the best demonstrated alternative processes, process changes, in-plant control measures, and end-of-pipe wastewater treatment technologies that reduce pollution to the maximum extent feasible in establishing NSPS.

PSES

Pretreatment standards for existing sources are designed to prevent the discharge of pollutants which pass through, interfere with, or are otherwise incompatible with the operation of POTWs. The Agency also requires pretreatment for pollutants that pass through POTWs due to the pollutants exhibiting significant volatilization prior to treatment by a POTW. The transfer of a pollutant to another media (air) through volatilization does not constitute treatment. PSES are technology-based and analogous to BAT for the control of priority and nonconventional pollutants.

PSNS

Pretreatment standards for new sources are designed to prevent the discharge of pollutants that pass through, interfere with, or are otherwise incompatible with the operation of POTWs. The CWA requires pretreatment for pollutants that pass through POTWs or limit POTW sludge management alternatives, including the beneficial use of sludges on agricultural lands.

The development of regulatory options for PSNS is analogous to the development of options for NSPS, in that the new source has the opportunity to design and install the best and most efficient manufacturing processes and wastewater treatment facilities. Accordingly, Congress directed EPA to consider the best demonstrated alternative processes, process changes, in-plant control measures, and end-of-pipe wastewater treatment technologies that reduce pollution to the maximum extent feasible in developing PSNS.

5.1.2 Model Technologies That Form the Bases of Effluent Limitations Guidelines and Standards

The effluent limitations guidelines and standards developed for the pharmaceutical manufacturing industry are based on the performance of several model technologies. Facilities are not required to use any specific technology, but rather may use any combination of pollution prevention, source reduction, process changes and internal controls, and treatment technology in order to comply with the effluent limitations guidelines and standards.

The model technology basis of BPT for facilities in subparts A and C is advanced biological treatment. BPT limitations under subparts A and C also include revised monitoring requirements for cyanide. The model technology basis of BPT for facilities in subparts B and D is advanced biological treatment. BCT limitations are the same as the BPT limitations for the conventional pollutants BOD_5, TSS and pH. The BCT model technologies are therefore the same as those under BPT.

The model technology basis of BAT and NSPS for facilities in subparts A and C is advanced biological treatment with nitrification. Nitrification is required for facilities in subparts A and C for control of ammonia. BAT and NSPS limitations under subparts A and C also include revised monitoring requirements for cyanide. The model technology basis of BAT and NSPS for facilities in subparts B and D is advanced biological treatment.

For indirect dischargers, the model technology basis of PSES and PSNS for facilities in subparts A and C is in-plant stream stripping for the volatile organic pollutants and either steam stripping or biological treatment with nitrification for ammonia control. The model technology basis of PSES and PSNS for facilities in subparts B and D is in-plant steam stripping.

The amended regulations removed the cyanide limitations which previously applied to both direct and indirect discharging subpart B and D facilities. Cyanide limitations based on alkaline chlorination for direct and indirect subpart A and C facilities were not revised. The 1998 amendments revised the monitoring requirements for cyanide for facilities with subpart A and C operations to clarify the effluent limitations guidelines compliance point.

Table 5-1 outlines the model technologies used to form the regulatory basis of BPT, BCT, BAT, NSPS, PSES, and PSNS. **For a complete description of each technology element, refer to the *Technical Development Document for Effluent Limitations Guidelines and Standards for the Pharmaceutical Manufacturing Point Source Category*, EPA-821-R-98-005.**

Table 5-1: Technology Basis for BPT, BAT, NSPS, PSES, and PSNS

Regulation	Technology Basis	
	Subpart A and C Facilities	**Subpart B and D Facilities**
BPT	Advanced biological treatment	Advanced biological treatment
BCT	Advanced biological treatment	Advanced biological treatment
BAT	Advanced biological treatment with nitrification	Advanced biological treatment
NSPS	Advanced biological treatment with nitrification	Advanced biological treatment
PSES	In-plant steam stripping for organic compounds, in-plant steam stripping or nitrification for ammonia	In-plant steam stripping for organic compounds
PSNS	In-plant steam stripping for organic compounds, in-plant steam stripping or nitrification for ammonia	In-plant steam stripping for organic compounds

6. Where Are Facilities Required to Demonstrate Compliance?

This section discusses where a pharmaceutical manufacturing facility with subpart A, B, C, D, and E operations should monitor to establish compliance.

The BPT, BAT, and NSPS effluent limitations guidelines and standards for wastewaters from subpart A, B, C, D, and E operations for ammonia, COD, cyanide, conventional pollutants as well as for priority and nonconventional organic pollutants are end-of-pipe limitations. A facility would normally measure for purposes of demonstrating compliance with the BPT, BAT and NSPS limitations and standards at the end-of-pipe monitoring point. However, in cases where a pollutant that is known to be present in the influent to the treatment system cannot be detected using approved analytical methods at the end-of-pipe monitoring point because of dilution from process and non-process wastewater not containing that pollutant, EPA regulations provide that a facility should monitor at a point before the dilution occurs. One case where upstream or in-plant monitoring may be required is in the case of compliance monitoring for the pollutant cyanide. In the study supporting the final pharmaceutical regulations, EPA found that eight of ten facilities monitored their cyanide-bearing waste streams for compliance at a point immediately after the cyanide destruction or treatment process occurs. This was the case because the flows of the cyanide-bearing waste streams were so small in relation to the remainder of the effluents at these facilities that end-of-pipe measurement of cyanide is not practical or feasible using approved analytical methods for measuring cyanide.

Similarly, the normal monitoring point for all pollutants controlled by the final pretreatment standards (PSES and PSNS) would be the end-of-pipe monitoring point. However, upstream or in-plant compliance monitoring may be required for any regulated pollutant in cases where it is not practical or feasible to monitor for a given pollutant at the end-of-pipe monitoring point. Dilution with large amounts of process and non-process wastewater may prevent detection of a pollutant at the end-of-pipe monitoring point. As a result, the permitting or control authority cannot determine whether the reduction in the concentration of a pollutant is the result of dilution or treatment. Consequently, a facility should monitor at a point before dilution occurs. Another case where in-plant monitoring may be necessary involves a situation where a pollutant is generated at a concentration below the regulatory levels and consequently does not require treatment. In such cases, it may be necessary to monitor at the point where the pollutant is introduced into the wastewater. In general, the monitoring point for a given pollutant should be where compliance is achieved through treatment and not dilution.

7. What are the Effluent Limitations Guidelines and Standards for Subparts A, B, C, D, and E?

This section presents the numerical effluent limitations guidelines and standards for subparts A, B, C, D, and E. Tables 7-1 through 7-7 list the applicable numerical effluent limitations guidelines and standards by discharge status and subpart.

7.1 Direct Dischargers

7.1.1 BPT, BAT and NSPS

This section lists the BPT, BAT, and NSPS effluent limitations guidelines and standards promulgated for direct dischargers with operations in subparts A, B, C, D, and E.

Table 7-1: BPT Effluent Limitations Guidelines for Direct Dischargers

Subpart	Pollutant or Property	BPT Effluent Limitations for End-of-Pipe Monitoring Points	
		Maximum for any one day (mg/L)	Monthly Average (mg/L) [a]
A - Fermentation Operations	COD	1,675	856
B - Biological and Natural Extraction Operations	COD	228	86
C - Chemical Synthesis Operations	COD	1,675	856
D - Mixing, Compounding, or Formulating Operations	COD	228	86
E - Research	COD	---	0.26 × raw waste × 2.2 **or** 220 mg/L (whichever is greater)

[a] For subparts A, B, C, and D, if the average monthly COD concentrations are higher than concentration values reflecting a reduction in the long-term average daily COD load in the raw (untreated) process wastewater of 74% multiplied by a variability factor of 2.2, then the effluent limitations for COD corresponding to the lower concentration values must be applied.

BAT effluent limitations for subparts A and C are presented in Table 7-2. BAT effluent limitations for subparts B and D are presented in Table 7-3. There are no BAT limitations for subpart E operations.

Table 7-2: BAT Effluent Limitations Guidelines for Subpart A and C Operations

Pollutant or Pollutant Property	Maximum for any one day (mg/L)	Monthly Average (mg/L)
BAT Effluent Limitation for In-Plant Monitoring Points		
Cyanide	33.5	9.4
BAT Effluent Limitations for End-of-Pipe Monitoring Points		
COD	1,675	856 [(a)]
Ammonia as N	84.1	29.4
Acetone	0.5	0.2
Acetonitrile	25.0	10.2
n-Amyl Acetate	1.3	0.5
Amyl Alcohol	10.0	4.1
Benzene	0.05	0.02
n-Butyl Acetate	1.3	0.5
Chlorobenzene	0.15	0.06
Chloroform	0.02	0.013
o-Dichlorobenzene	0.15	0.06
1,2-Dichloroethane	0.4	0.1
Diethylamine	250.0	102.0
Dimethyl Sulfoxide	91.5	37.5
Ethanol	10.0	4.1
Ethyl Acetate	1.3	0.5
n-Heptane	0.05	0.02
n-Hexane	0.03	0.02
Isobutyraldehyde	1.2	0.5
Isopropanol	3.9	1.6
Isopropyl Acetate	1.3	0.5
Isopropyl Ether	8.4	2.6
Methanol	10.0	4.1
Methyl Cellosolve	100.0	40.6
Methylene Chloride	0.9	0.3
Methyl Formate	1.3	0.5
MIBK	0.5	0.2
Phenol	0.05	0.02
Tetrahydrofuran	8.4	2.6
Toluene	0.06	0.02
Triethylamine	250.0	102.0
Xylenes	0.03	0.01

[(a)] If the average monthly COD concentrations are higher than concentration values reflecting a reduction in the long-term average daily COD load in the raw (untreated) process wastewater of 74% multiplied by a variability factor of 2.2, then the average monthly effluent limitations for COD corresponding to the lower concentration values must be applied.

Table 7-3: BAT Effluent Limitations Guidelines for Subpart B and D Operations

Pollutant or Pollutant Property	BAT Effluent Limitation for End-of-Pipe Monitoring Points	
	Maximum for any one day (mg/L)	Monthly Average (mg/L)
COD	228	86

NSPS for subparts A and C are presented in Table 7-4. NSPS for subparts B and D are presented in Table 7-5. There are no NSPS limitations for subpart E operations.

Table 7-4: NSPS for Subpart A and C Operations

Pollutant or Pollutant Property	Maximum for any one day (mg/L)	Monthly Average (mg/L)
NSPS for In-Plant Monitoring Points		
Cyanide [(a)]	33.5	9.4
NSPS for End-of-Pipe Monitoring Points		
BOD_5	267	111
COD	1,675	856
TSS	472	166
Ammonia as N	84.1	29.4
Acetone	0.5	0.2
Acetonitrile	25.0	10.2
n-Amyl Acetate	1.3	0.5
Amyl Alcohol	10.0	4.1
Benzene	0.05	0.02
n-Butyl Acetate	1.3	0.5
Chlorobenzene	0.15	0.06
Chloroform	0.02	0.013
o-Dichlorobenzene	0.15	0.06
1,2-Dichloroethane	0.4	0.1
Diethylamine	250.0	102.0
Dimethyl Sulfoxide	91.5	37.5
Ethanol	10.0	4.1
Ethyl Acetate	1.3	0.5
n-Heptane	0.05	0.02
n-Hexane	0.03	0.02
Isobutyraldehyde	1.2	0.5
Isopropanol	3.9	1.6
Isopropyl Acetate	1.3	0.5
Isopropyl Ether	8.4	2.6
Methanol	10.0	4.1

Pollutant or Pollutant Property	Maximum for any one day (mg/L)	Monthly Average (mg/L)
Methyl Cellosolve	100.0	40.6
Methylene Chloride	0.9	0.3
Methyl Formate	1.3	0.5
MIBK	0.5	0.2
Phenol	0.05	0.02
Tetrahydrofuran	8.4	2.6
Toluene	0.06	0.02
Triethylamine	250.0	102.0
Xylenes	0.03	0.01

[(a)] Cyanide effluent limit established in the 1983 final rule.

Table 7-5: NSPS for Subpart B and D Operations

Pollutant or Pollutant Property	NSPS for End-of-Pipe Monitoring Points	
	Maximum for any one day (mg/L)	Monthly Average (mg/L)
BOD_5	35	18
COD	228	86
TSS	58	31

7.2 Indirect Dischargers

7.2.1 PSES and PSNS

This section lists PSES and PSNS for existing and new indirect dischargers with operations in subparts A, B, C, and D. Subpart E operations are not regulated by PSES or PSNS.

EPA did not revise the existing PSES standards for cyanide for subpart A and C facilities. EPA did regulate organics and ammonia, and clarified the current cyanide monitoring requirements for these facilities.

EPA set pretreatment standards for ammonia for subparts A and C because of the high loads of ammonia currently being discharged by a number of pharmaceutical facilities to POTWs that do not have nitrification capability and receive wastewaters from subpart A and C facilities. However, EPA is aware that some POTWs treating pharmaceutical wastewaters from these subcategories have nitrification capability, and EPA has made a determination of no pass through for ammonia at these POTWs. Thus, PSES ammonia limitations will not apply to subpart A and C facilities discharging to POTWs with nitrification capability. POTWs that nitrify should impose local limits for ammonia if they believe that the ammonia load from the pharmaceutical industrial user(s) will nevertheless pass through their facilities. POTWs with nitrification capability are defined as being able to oxidize ammonium salts to nitrites (via *Nitrosomonas sp*. bacteria) and then further oxidize nitrites to nitrates (via *Nitrobacter sp*. bacteria) and achieve greater removals of ammonia than POTWs without nitrification. Nitrification can be accomplished in either a single- or two-stage activated sludge system. Indicators of nitrification capability are: (1) biological monitoring for ammonia oxidizing bacteria (AOB) and nitrite oxidizing bacteria (NOB) to nitrite oxidizing bacteria (NOB) to determine if nitrification is occurring; or (2) analysis of the nitrogen balance

across the biological treatment unit(s) to determine if nitrifying bacteria reduce the amount of ammonia and increase the amount of nitrite and nitrate in the wastewater. At POTWs where the nitrogen balance is not usable because nitrites and nitrates are not present in the effluent in significant concentrations, such as at a POTW with nitrification-denitrification treatment or one with a wetlands treatment unit, the identification of the AOB and NOB will demonstrate that nitrification is occurring. Thus, the use of one of the aforementioned methods is sufficient for demonstrating nitrification capability.

The PSES and PSNS for subpart A and C operations are presented in Table 7-6. The PSES and PSNS for subpart B and D operations are presented in Table 7-7.

Table 7-6: PSES and PSNS for Subpart A and C Operations

Pollutant or Pollutant Property	Maximum for any one day (mg/L)	Monthly Average (mg/L)
PSES/PSNS for In-Plant Monitoring Points		
Cyanide [(a)]	33.5	9.4
PSES/PSNS for End-of-Pipe Monitoring Points		
Ammonia as N [(b)]	84.1	29.4
Acetone	20.7	8.2
n-Amyl Acetate	20.7	8.2
Benzene	3.0	0.6
n-Butyl Acetate	20.7	8.2
Chlorobenzene	3.0	0.7
Chloroform	0.1	0.03
o-Dichlorobenzene	20.7	8.2
1,2-Dichloroethane	20.7	8.2
Diethylamine	255.0	100.0
Ethyl Acetate	20.7	8.2
n-Heptane	3.0	0.7
n-Hexane	3.0	0.7
Isobutyraldehyde	20.7	8.2
Isopropyl Acetate	20.7	8.2
Isopropyl Ether	20.7	8.2
Methylene Chloride	3.0	0.7
Methyl Formate	20.7	8.2
MIBK	20.7	8.2
Tetrahydrofuran	9.2	3.4
Toluene	0.3	0.2
Triethylamine	255.0	100.0
Xylenes	3.0	0.7

[(a)] Cyanide effluent limit established in the 1983 final rule.
[(b)] Ammonia is only regulated for indirect dischargers that discharge to non-nitrifying POTWs.

Table 7-7: PSES and PSNS for Subpart B and D Operations

Pollutant or Pollutant Property	PSES/PSNS for End-of-Pipe Monitoring Points	
	Maximum for any one day (mg/L)	Monthly Average (mg/L)
Acetone	20.7	8.2
N-Amyl acetate	20.7	8.2
Ethyl acetate	20.7	8.2
Isopropyl acetate	20.7	8.2
Methylene chloride	3.0	0.7