Case Studies

Because there are complex permitting issues associated with 40 CFR Part 439, this section presents four case studies showing the development of NPDES and pretreatment authority permits for facilities subject to BPT, BAT, and PSES under subparts A, B, C, D, and E. The case studies cover a variety of facility types and complexity. Each case study presents the following: # Facility's current permit status; # General site description; # Information about facility operations relevant to establishing permit limits; # Step-by-step approach to determining limits for each regulation (e.g., BPT, BAT); and # Final limits as they would appear in each example facility's permit.

9.1 Case Study #1

Facility A is an existing multiple-subcategory, direct discharging pharmaceutical manufacturing facility which has on-site treatment and discharges to the Blue River. The facility has submitted an application for a new NPDES permit.

9.2 Case Study #2

Facility B is an existing multiple-subcategory indirect discharging pharmaceutical manufacturing facility which discharges to a municipal POTW.

9.3 Case Study #3

Facility C is an existing multiple-subcategory, direct discharging pharmaceutical manufacturing facility which has on-site treatment and discharges to the Red River. The facility has submitted an application for a new NPDES permit.

9.4 Case Study #4

Facility D is a direct discharging manufacturing facility with operations in two industrial categories. This facility manufactures pharmaceuticals as well as bulk organic chemicals.

9. Case Studies

Because there are complex permitting issues associated with 40 CFR Part 439, this section presents four case studies showing the development of NPDES and pretreatment authority permits for facilities subject to BPT, BAT, and PSES under subparts A, B, C, D, and E. The case studies cover a variety of facility types and complexity. Each case study presents the following:

- Facility's current permit status;
- General site description;
- Information about facility operations relevant to establishing permit limits;
- Step-by-step approach to determining limits for each regulation (e.g., BPT, BAT); and
- Final limits as they would appear in each example facility's permit.

9.1 Case Study #1

Facility A is an existing multiple-subcategory, direct discharging pharmaceutical manufacturing facility which has on-site treatment and discharges to the Blue River. The facility has submitted an application for a new NPDES permit.

Case Study #1 highlights:

1. Permit process for direct discharging facility with operations in subparts A, C, D, and E.
2. Dilution water is less than 25% of facility flow.

9.1.1 General Site Description

The flow schematic for Facility A shows the flow from each operation, and is presented in Figure 9-1.

9.1.2 Relevant Information for Establishing Permit Limits

Table 9-1 summarizes the information from the permit application needed to calculate discharge limits for the reissued NPDES permit.

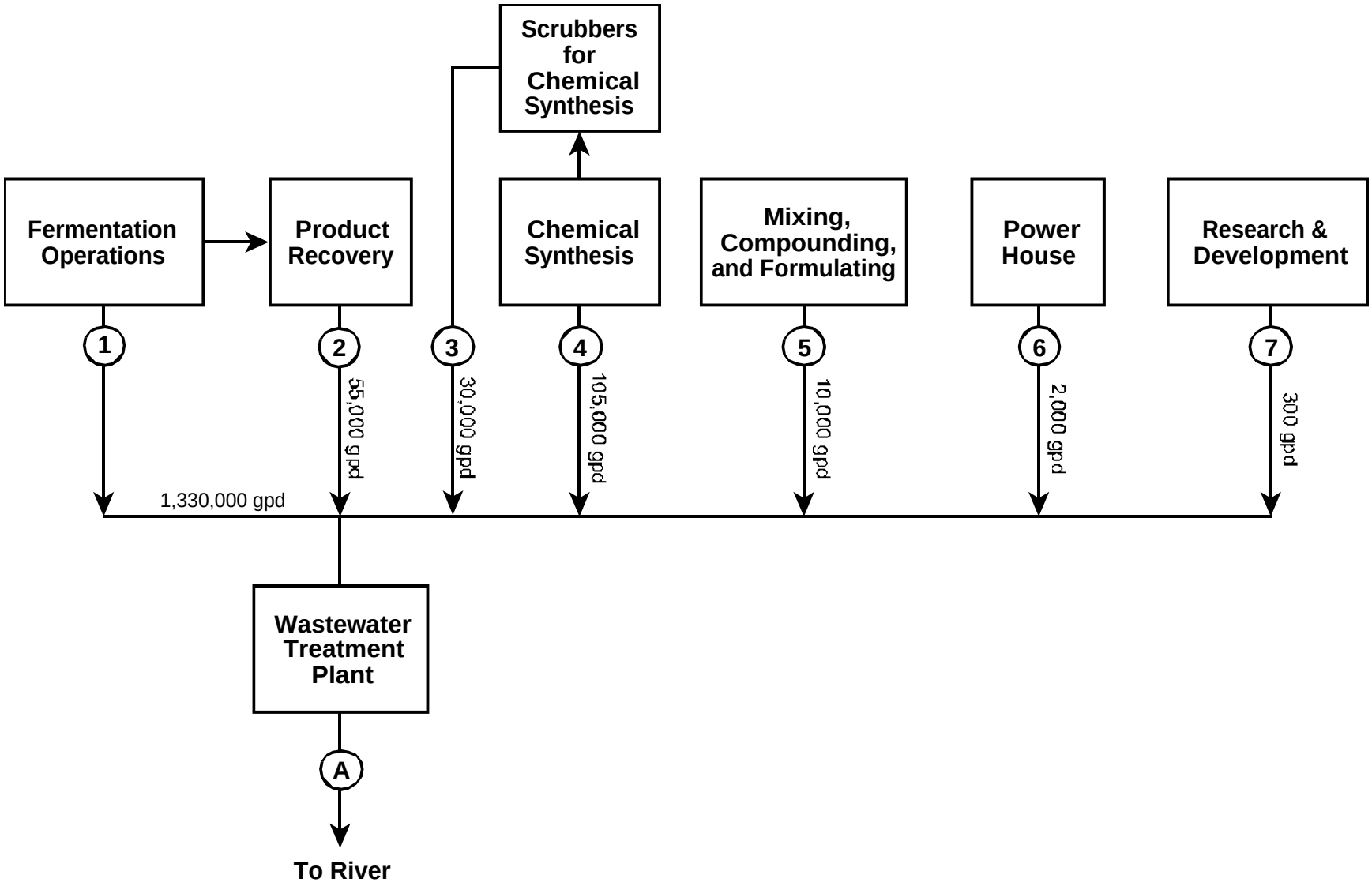

Figure 9-1: Flow Schematic for Facility A

Table 9-1: Information Needed to Establish Permit Limits for Case Study #1

What type of discharger is the facility?	Direct
Under which subparts do the facility's operations fall?	Subparts A, C, D, and E
The facility is subject to which effluent limitations guidelines and standards?	BPT (40 CFR Part 439) BCT (40 CFR Part 439) BAT (40 CFR Part 439)
Is the dilution water at the facility >25% of the total flow?	No

9.1.3 Determining Permit Limits for Pollutants Regulated Under BPT

The 1998 final BPT effluent limitations guidelines revised the 1983 COD effluent limitations for subpart A, B, C, and D operations at direct discharging facilities. In 1983, EPA promulgated COD effluent limitations guidelines requiring 74% reduction in the long-term daily COD load in the raw (untreated) wastewater multiplied by a variability factor of 2.2. Under the 1998 revised BPT COD regulations, facilities must comply with the new COD concentration limitations or the 1983 BPT regulations, whichever is more stringent. Which limitation applies is determined by comparing the monthly average effluent limitations specified by the 1998 and 1983 limitations. The BPT effluent limitations guidelines for BOD_5, TSS and pH were not changed. The BPT effluent limitations guidelines for subpart E operations are established in the 1983 final rule. The other conventional pollutants, fecal coliform and oil & grease, are not regulated by BPT for the pharmaceutical manufacturing point source category.

The effluent limitations guidelines are concentration-based and, as such, do not regulate wastewater flow. The permit writer must use a reasonable estimate of process wastewater discharge flow and the concentration-based limitations to develop mass-based limitations for the NPDES permit. Table 7-1 presents the maximum daily and monthly average BPT effluent limitations for subpart A, B, C, D, and E operations at direct discharging facilities.

The limitations for COD will be applied to the final effluent. An example calculation of the BPT maximum for any one day and monthly average COD limitations for this facility is shown in the following sections.

Step 1. Determining Allowable Wastewater Discharge Flow

The first step in establishing permit limitations is to determine the types of wastestreams (i.e., regulated process, unregulated process, and dilute) at the facility. The flow breakdown for Facility A is shown in Table 9-2.

Table 9-2: Flow Breakdown for Facility A

Waste Stream		Flow (gal/day)	
1.	Fermentation operations	1,330,000	(Regulated, subpart A)
2.	Product recovery	55,000	(Regulated, subpart A)
3.	In-plant scrubbers for chemical synthesis	30,000	(Regulated, subpart C)
4.	Chemical synthesis	105,000	(Regulated, subpart C)
5.	Mixing/compounding and formulation	10,000	(Regulated, subpart D)
6.	Power house boiler blowdown	2,000	(Dilute)
7.	Research and development	300	(Regulated, subpart E)*
Total wastewater flow:		1,532,300	
Total regulated process flow:		1,530,300	
Total dilute flow:		2,000	

*For monthly average limitations only

Under BPT, streams 1, 2, 3, 4, 5, and 7 are considered regulated wastestreams as effluent limitations have been established for fermentation operations (subpart A), chemical synthesis operations (subpart C), formulating operations (subpart D), and research operations (subpart E). Air pollution control wastewaters are considered process wastewaters corresponding to the subcategory operations the air pollution control devices control. Stream 6 is considered to be dilution stream.

Using BPJ, the permit writer determines Facility A's annual average wastewater discharge. Assuming the facility production and wastewater flow are not expected to change significantly during the permit term, the historical data provided by Facility A are used to establish the annual discharge flow, which is then used to develop mass-based effluent limitations. If wastewater stream 6 is commingled with the process waste streams prior to treatment, the allowable WW discharge flow used to calculate the mass -based limitations is calculated as follows:

Process WW discharge	=	1,530,300 gal/day
Allowable WW discharge	=	(0.25) Allowable WW discharge + Process WW discharge
(1 - 0.25)Allowable WW discharge	=	Process WW discharge
Allowable WW discharge	=	Process WW discharge / (0.75)
	=	1,530,300 gal/day / (0.75)
	=	2,040,400 gal/day

The allowable wastewater discharge flow used to establish the COD mass-based limitations can include up to (2,040,400 - 1,530,300) = 510,100 gallons per day of non-process wastewater before this water would be considered as dilution water. Facility A has only 2,000 gallons per day of nonprocess wastewater and, therefore, has less than 25 % nonprocess water in the final effluent. Thus, the total effluent flow of 1,532,300 gal/day will be used to establish the COD mass-based limitations.

Table 7-1 presents the maximum daily and monthly average BPT effluent limitations for subpart A, B, C, and D operations at direct discharging facilities. The BPT limitations for subparts A and C are the same and the limitations for subparts B and D are the same. Daily maximum limitations have not been promulgated for subpart E operations. Monthly average limitations for subpart E operations have been promulgated and are found at 40 CFR 439.52.

To calculate the mass limits for the allowable nonprocess water, concentration limits for each subpart are applied to a percentage of the total allowable nonprocess water flow. The allowable nonprocess water flow is divided between subcategories based on the subpart A and C and subpart B and D process flow compared to the total process flow. The calculation for Facility A is shown below:

Subpart A and C process water flow
= 1,330,000 + 55,000 + 30,000 + 105,000 gal/day = 1,520,000 gal/day

Subpart B and D process water flow
= 10,000 gal/day

Total process water flow
= 1,520,000 + 10,000 gal/day = 1,530,000 gal/day

Allowable nonprocess water flow:

Subpart A and C concentration limits apply

$$= \frac{1{,}520{,}000 \text{ gal/day}}{1{,}530{,}000 \text{ gal/day}} \times 2{,}000 \text{ gal/day} = 1{,}987 \text{ gal/day}$$

Subpart B and D concentration limits apply

$$= \frac{10{,}000 \text{ gal/day}}{1{,}530{,}000 \text{ gal/day}} \times 2{,}000 \text{ gal/day} = 13 \text{ gal/day}$$

When calculating mass-based effluent limitations, 1,987 gallons per day of nonprocess water should be multiplied by the subpart A and C concentration limits, and 13 gallons per day of nonprocess water should be multiplied by the subpart B and D concentration limits.

Step 2. Determining the Use of Monthly Average Limitations vs. Percent Reduction for COD Limitations

Facility A must comply with either the revised COD concentration limitations or the previously promulgated COD limit requiring a reduction in the long-term average daily COD load in the raw (untreated) process wastewater of 74 percent multiplied by a variability factor of 2.2, whichever is more stringent. Permit authorities should compare the revised monthly average effluent limitations, which apply to subpart A, B, C and D operations, with the previously promulgated guidelines to determine which is more stringent. As mentioned previously, monthly average limitations for subpart E operations were not revised in the 1998 final rule; the effluent limitations guidelines presented in 40 CFR 439.52 requiring a 74 percent reduction in the long-term daily COD load or an average monthly discharge of 220 mg/L, whichever is greater, continue to apply.

Assuming subpart A, B, C and D operations at Facility A have an influent COD concentration of 2,000 mg/L in the wastewater treatment plant, a 74 percent reduction in the long-term daily COD load multiplied by a variability factor of 2.2 would result in a final effluent discharge limitation of 1,144 mg/L. The revised COD limitations require a maximum monthly average of 856 mg/L for subpart A and C operations and 86 mg/L for subpart B and D operations. The revised COD limitations are more stringent, and therefore Facility A must comply with the mass-based limitations derived from the concentration-based COD limitations promulgated in 1998.

For subpart E operations, the percent reduction or the floor limitation of 220 mg/l, whichever is greater, will continue to apply. Assuming Facility A has a COD concentration of 250 mg/L from subpart E operations, a 74 percent reduction in the long-term daily COD load multiplied by a variability factor of 2.2 results in an average effluent discharge limitation of 143 mg/L. Since the floor limitation of 220 mg/l is greater, the 220 mg/l limitation will apply to subpart E wastewater.

The total monthly average BPT COD limitations can be calculated as follows:

Subpart A and C limitations:

856 mg/L × (1,520,000 + 1,987) gal/day × [8.345 × 10^{-6} (L × lb)/(gal × mg)]
= 10,872 lbs/day

Subpart B and D limitations:

86 mg/L × (10,000 + 13) gal/day × [8.345 × 10^{-6} (L × lb)/(gal × mg)]
= 7.2 lbs/day

Subpart E limitations:

220 mg/L × 300 gal/day × [8.345 × 10^{-6} (L × lb)/(gal × mg)]
= 0.55 lbs/day

TOTAL = 10,880 lbs/day

The monthly average effluent limitation for COD in the combined waste stream would be 10,880 lbs/day. This monthly average limitation is compared to the average of all daily mass discharge amounts in a calendar month to determine facility compliance.

Step 3. Determining Maximum Effluent Limitations for Any One Day

Daily maximum effluent limitations can be calculated using the same calculations performed for the monthly average effluent limitations. For our example, Facility A includes subpart E operations (waste stream 7). Since maximum limitations for any one day have not been promulgated for subpart E operations, waste stream 7 is considered an unregulated waste stream in the calculation of daily maximum limitations and can be combined with the other dilute stream (waste stream 6) for the calculation as follows:

Allowable nonprocess water flow:

Subpart A and C concentration limits apply

$$= \frac{1{,}520{,}000 \text{ gal/day}}{1{,}530{,}000 \text{ gal/day}} \times 2{,}300 \text{ gal/day} = 2{,}285 \text{ gal/day}$$

Subpart B and D concentration limits apply

$$= \frac{10{,}000 \text{ gal/day}}{1{,}530{,}000 \text{ gal/day}} \times 2{,}300 \text{ gal/day} = 15 \text{ gal/day}$$

The total BPT COD maximum allowable discharge for any one day can be calculated as follows:

Subpart A and C limitations:

1,675 mg/L × (1,520,000 + 2,285) gal/day × [8.345 × 10^{-6} (L × lb)/(gal × mg)]
= 21,278 lbs/day

Subpart B and D limitations:

228 mg/L × (10,000 + 15) gal/day × [8.345 × 10^{-6} (L × lb)/(gal × mg)]
= 19 lbs/day

TOTAL = 21,297 lbs/day

Therefore, the maximum for any one day effluent limitations for COD in the combined wastestream would be 21,297 lbs/day.

9.1.4 Determining Permit Limits for Pollutants Regulated Under BAT

Tables 7-2 and 7-3 present the maximum daily and monthly average BAT effluent limitations guidelines for subparts A and C, and subparts B and D, respectively. BAT for ammonia and the organic pollutants listed in these tables are applicable to the final effluent discharged to the waters of the United States.

Previously promulgated BAT limitations for cyanide are also presented in Table 7-2 and are applicable to subpart A and C operations. Compliance monitoring for cyanide should occur immediately after cyanide destruction, before commingling cyanide-bearing wastestreams with noncyanide-bearing wastestreams, unless a facility can demonstrate that cyanide is detectable at the end-of-pipe sampling point and applicable information exists to use the end-of-pipe monitoring results to determine compliance. In-plant monitoring is required at those facilities unable to detect cyanide at the end-of-pipe monitoring point.

We will assume that Facility A has provided the permit writer with an accurate characterization of its process wastestreams by means available such as solvent use and disposition data, and chemical analysis of each stream. Permit writers should establish permit limitations and require compliance monitoring for each regulated pollutant generated or used at a pharmaceutical manufacturing facility. Routine compliance monitoring is not required for regulated pollutants not generated or used at a facility. Facilities should make a determination that regulated pollutants are not generated or used based on a review of all raw materials used, and an assessment of all chemical processes used, and consideration of resulting products and by-products. The determination that a regulated pollutant is not generated or used should be confirmed by annual chemical analyses of wastewater from each monitoring location, and these analyses must be submitted to the permit writer. Such confirmation is provided if the pollutant is not detected above the ML of an EPA-approved analytical method.

Table 9-3 presents a summary of the regulated pollutants expected to be found in this facility's waste streams:

Table 9-3: Regulated Organic Pollutants Found in the Wastewater of Facility A

Stream	Subpart	Flow (gal/day)	Pollutant
1	A	1,330,000	Methylene chloride, acetone
2	A	55,000	Methylene chloride, acetone
3	C	30,000	Methylene chloride, acetone
4	C	105,000	Methylene chloride, acetone
5	D	10,000	No regulated organic pollutants
6	N/A	2,000	No regulated organic pollutants
7	E	300	No regulated organic pollutants

Based on the above data, permit writers should use reasonable estimates of the process discharge flow, allowing generally for up to 25% nonprocess wastewater, and the concentration-based standards in Tables 7-3 and 7-4 to develop limitations for methylene chloride and acetone.

Subpart B, D, and E wastewater is unregulated for organic pollutants. However, EPA's NPDES regulations generally require consideration of dilution water in establishing limitations. See 40 CFR 122.45 (f)(1)(iii). Thus, the permit writer should determine whether unregulated streams should be considered dilution. For this example, subpart D (stream 5) and subpart E (stream 7) are considered unregulated process wastewater, and the permit authority may use BPJ to calculate limits to account for the organic pollutants present in these streams.

Step 1. Determining BAT Maximum Limitations for Any One Day for Organic Pollutants and COD

As shown in Table 7-2, the following maximum for any one day limitations apply for subpart A and C operations:

Methylene chloride:	0.9 mg/L
Acetone:	0.5 mg/L

Methylene chloride and acetone are present only in waste streams in which organic pollutants are regulated (i.e. subpart A and C waste streams). The allowable wastewater flow for Facility A is calculated as shown below.

Process wastewater flow (regulated subpart A and C):
= Stream 1 (subpart A) + Stream 2 (subpart A) + Stream 3 (subpart C) + Stream 4 (subpart C)
= (1,330,000 + 55,000 + 30,000 + 105,000) gal/day
= 1,520,000 gal/day

Allowable wastewater flow:
= Process wastewater flow/(0.75)
= 1,520,000 gal/day/(0.75)
= 2,026,667 gal/day

Total nonprocess wastewater flow, including unregulated process wastewater (subpart B, D, and E operations):

= Stream 5 (subpart D) + Stream 6 (dilution) + Stream 7 (subpart E)
= (10,000 + 2,000 + 300) gal/day = 12,300 gal/day

The allowable wastewater flow for calculating BAT mass-based effluent limitations is 2,026,667 gal/day. Facility A's total flow of 1,532,300 gal/day does not exceed this allowance and the total discharge flow can be used to calculate effluent limitations.

The daily maximum mass-based effluent limitation for acetone is calculated as follows:

$$L_m = L_c \times F \times k_1$$
$$= 0.5 \text{ mg/L} \times 1{,}532{,}300 \text{ gal/day} \times [8.345 \times 10^{-6} \text{ (L} \times \text{lb)/(gal} \times \text{mg)}]$$
$$= 6.39 \text{ lbs/day}$$

The total facility maximum daily discharge limitation for acetone is 6.39 lbs/day. The maximum daily effluent limitations for methylene chloride can be calculated in a similar manner.

The maximum one day effluent limitation for COD under BAT is the same as the limitation set under BPT. Therefore, the resulting COD daily maximum mass-based effluent limitation is 21,297 lbs/day as calculated above for BPT.

Step 2. Determining BAT Monthly Average Limitations for Organic Pollutants and COD

The monthly average limitations for Facility A are calculated in a similar manner as the maximum daily effluent limitations. The following monthly average effluent limitations are presented in Table 7-2 and apply to subpart A and C operations:

Methylene chloride:	0.3 mg/L
Acetone:	0.2 mg/L

The allowable wastewater discharge flow of 2,026,667 gallons per day applies in the calculated mass-based effluent limitations for acetone and methylene chloride, as calculated previously. For Facility A, the monthly average mass-based limitation calculation for methylene chloride is shown below:

$$L_m = L_c \times F \times k_1$$
$$= 0.3 \text{ mg/L} \times 1{,}532{,}300 \text{ gal/day} \times [8.345 \times 10^{-6} \text{ (L} \times \text{lb)/(gal} \times \text{mg)}]$$
$$= 3.84 \text{ lbs/day}$$

The monthly average discharge limitation for methylene chloride = 3.84 lbs/day.

This monthly average limitation is compared to the average of all daily discharge amounts in a calendar month to determine facility compliance. The monthly average effluent limitations for acetone can be calculated in a similar manner.

The monthly average limitation for COD under BAT is the same as the limitation set under BPT. Therefore, the resulting COD monthly average mass-based effluent limitation is 10,880 lbs/day as calculated above for BPT.

Step 3. Determining Compliance Monitoring for BAT Pollutants

For our example, Facility A should perform compliance monitoring at Point A prior to discharge into the Blue River.

Facilities discharging more than one regulated pollutant may request to monitor for a single surrogate pollutant to demonstrate an appropriate degree of control for a specified group of pollutants. For the purpose of identifying surrogates, pollutants have been grouped according to treatability classes; Table 8-1 presents the treatability classes identified for advanced biological treatment. The choice of surrogate pollutant, when multiple pollutants are appropriate, can be based on the pollutant with the highest concentration. Ultimately, if the use of surrogates is requested by a facility, the permit writer may decide on a facility-by-facility basis whether surrogate pollutants are appropriate and which pollutant may be used as a surrogate. For Facility A, the two regulated organic pollutants in the facility's wastewater are not part of the same treatability class and use of a surrogate would not apply.

9.1.5 Final Limits as They Would Appear in a Permit for Facility A

Table 9-4 presents the final limits as they would appear in a permit for Facility A on a mass-basis. Permit writers can choose to show limits on a concentration-basis in addition to the mass-based limits.

Table 9-4: Final Limits for Facility A

Pollutant or Pollutant Property [(a)]	Effluent Limitations for In-Plant and End Of Pipe (EOP) Monitoring Points		
	Maximum for any one day (lb/day)	Monthly Average (lb/day)	Monitoring Point
Chemical Oxygen Demand (COD)	21,297	10,880	EOP
Acetone	6.39	2.56	EOP
Methylene chloride	11.5	3.84	EOP

[(a)] pH, BOD_5, and TSS limits are not shown here since they have not been changed by the September 21, 1998 promulgated rule. These limits would be calculated as they have been in the past.
The limitations presented in Table 9-4 would be effective on November 20, 1998 or upon reissuance of the current permit, whichever is later.

9.2 Case Study #2

Case Study #2 highlights:

1. Permit process for indirect discharging facility with operations in subparts C and D and the facility has pilot-scale operations under subpart E.
2. Concentration-based examples provided.

Facility B is an existing multiple-subcategory indirect discharging pharmaceutical manufacturing facility which discharges to a municipal POTW.

9.2.1 General Site Description

The flow schematic for Facility B shows the flow from each operation, and is presented in Figure 9-2.

9.2.2 Relevant Information for Establishing Permit Limits

Table 9-5 summarizes the information from the permit application needed to calculate discharge limits for the reissued pretreatment permit.

Table 9-5: Information Needed to Establish Permit Limits for Case Study #2

What type of discharger is the facility?	Indirect
Under which subparts do the facility's operations fall?	Subparts C, D and E
The facility is subject to which effluent limitations guidelines and standards?	PSES (40 CFR Part 439)

9.2.3 Determining Limits for Pollutants Regulated Under PSES

PSES has been revised for subparts A, B, C and D. The final effluent limitation standards are concentration-based and, as such, do not regulate wastewater flow. The limitations apply at the end-of-pipe, except for cyanide. If end-of-pipe measurement is infeasible, control authorities may set a monitoring point at a more suitable location. Compliance monitoring for cyanide should occur in-plant, prior to commingling with non-cyanide bearing wastewaters. EPA has regulated 24 priority and nonconventional pollutants (including ammonia, where applicable, and cyanide) for indirect dischargers in subparts A and C. The effluent limitations for subpart A and C operations are presented in Table 7-6. EPA has regulated five priority and nonconventional pollutants for indirect dischargers in subparts B and D. Table 7-7 presents the effluent limitations for subpart B and D operations.

The first step in establishing permit limitations is to determine the types of wastestreams (i.e., regulated process, unregulated process, and dilute). The flow breakdown for Facility B is shown in Table 9-6.

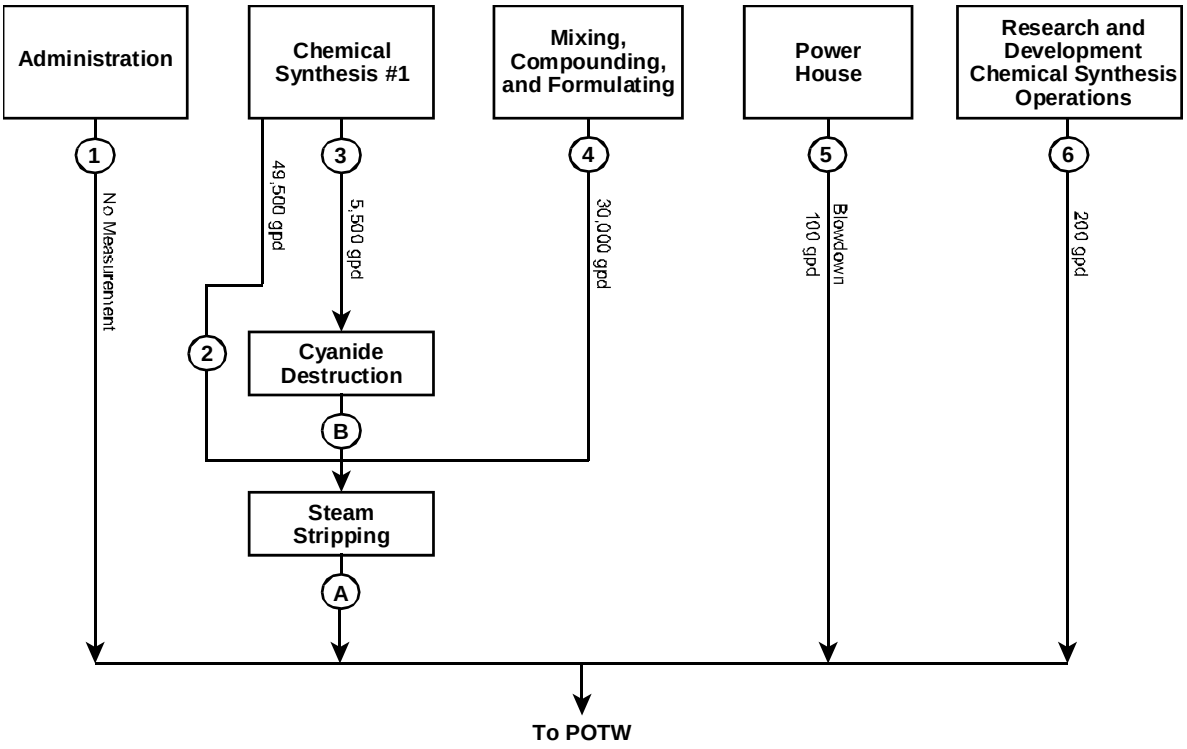

Figure 9-2: Flow Schematic for Facility B

Table 9-6: Flow Breakdown for Facility B

Waste Stream		Flow (gal/day)	
1.	Administration		No measurement
2.	Chemical synthesis	49,500	(Regulated, subpart C)*
3.	Cyanide-bearing chemical synthesis	5,500	(Regulated, subpart C)*
4.	Mixing/compounding and formulation	30,000	(Regulated, subpart D)*
5.	Power house boiler blowdown	100	(Dilute)
6.	Research and development chemical synthesis	200	(Unregulated, subpart E)
Total measured wastewater flow:		85,300	
Total regulated process flow:		85,000	
Total unregulated process flow:		200	

*Pollutants regulated at subpart C operations may not be regulated at subpart D operations.

Streams 2, 3, and 4 are regulated process wastestreams because effluent limitations have been established for chemical synthesis operations (subpart C) and mixing, formulating, and compounding operations (subpart D). However, only five pollutants are regulated at subpart D, therefore the facility may have a pollutant regulated in streams 2 and 3 but unregulated in stream 4.

We will assume that Facility B has provided the permit writer with an accurate characterization of its process wastestreams by means available such as solvent use and disposition data, and chemical analysis of each stream. Permit writers should establish permit limitations and require compliance monitoring for each regulated pollutant generated or used at a pharmaceutical manufacturing facility. Routine compliance monitoring is not required for regulated pollutants not generated or used at a facility. Facilities should make a determination that regulated pollutants are not generated or used based on a review of all raw materials used, and an assessment of all chemical processes used, and consideration of resulting products and by-products. The determination that a regulated pollutant is not generated or used should be confirmed by annual chemical analyses of wastewater from each monitoring location, and these analyses must be submitted to the permit writer. Such confirmation is provided if the pollutant is not-detected above the ML of an EPA-approved analytical method.

Table 9-7 presents a summary of regulated pollutants found in this facility's wastestreams:

Table 9-7: Regulated Pollutants Found in the Wastewater of Facility B

Stream	Subpart	Flow (gal/day)	Pollutant
1	N/A	Not Measured	No PSES pollutants
2	C	49,500	Acetone, chloroform, toluene
3	C	5,500	Acetone, cyanide
4	D	30,000	Acetone, isopropyl acetate, toluene
5	N/A	100	No PSES pollutants
6	E	200	Chloroform, toluene

Based on the above data, permit limitations would be established for acetone, chloroform, cyanide, isopropyl acetate, and toluene. Acetone and isopropyl acetate are regulated in wastewater discharges from subpart A, B, C, and D operations. Chloroform, cyanide and toluene are regulated in wastewater discharges from subpart A and C operations only.

Step 1. Determining PSES Maximum Limitations for Any One Day

In this case study, the total flow going to the POTW cannot be measured, as the amount of water from the administrative building cannot be determined. Thus, it is not possible to calculate the appropriate concentration of pollutants at the end of pipe. In this case study, the limitations for all pollutants except cyanide would be applied at monitoring point A. Cyanide limitations would apply in-plant at point B prior to any dilution or commingling with non-cyanide-bearing wastestreams unless the facility can show cyanide is detectable at point A.

Concentration-based limits for indirect discharging facilities are listed in Tables 7-6 and 7-7.

In our example, the following maximum for any one day effluent limitations apply:

Acetone:	20.7 mg/L (subpart C & D)
Chloroform:	0.1 mg/L (subpart C)
Cyanide:	33.5 mg/L (subpart C)
Isopropyl acetate:	20.7 mg/L (subpart C & D)
Toluene:	0.3 mg/L (subpart C)

The concentration-based limit for acetone is 20.7 mg/L for both subpart C and D operations. This limit would be applied at monitoring point A, after the steam-stripping unit operations on streams 2 and 3. Concentration-based limits for chloroform, isopropyl acetate, and toluene would be applied in a similar manner.

Step 2. Determining PSES Monthly Average Limitations

Concentration-based monthly average effluent limitations for each of the pollutants can be calculated in the same manner as the daily maximum effluent limitations. The following monthly average limitations apply for Facility B:

Acetone:	8.2 mg/L (subpart C and D)
Chloroform:	0.03 mg/L (subpart C)
Cyanide:	9.4 mg/L (subpart C)
Isopropyl acetate:	8.2 mg/L (subpart C and D)
Toluene:	0.2 mg/L (subpart C)

Facility B would show compliance by averaging the daily maximum values in a 30-day period and showing the monthly average concentrations as equal to or less than the numbers above. For this example, Facility B should perform compliance monitoring at point A on Figure 9-2 for all regulated pollutants, except cyanide.

Monthly average limitations for cyanide would be calculated using the flow from stream 3 of subpart C operations, as other streams do not contain cyanide. The concentration-based monthly average limitation is 9.4 mg/L. This monthly average limitation is compared to the average of daily discharge amounts in a calendar month to determine facility compliance. If only one sample is taken in the calendar month, the sample must meet both the daily maximum limitation and the monthly average limitation.

9.2.4 Determining Compliance Monitoring for PSES Pollutants

Facilities discharging more than one regulated pollutant may request to monitor for a single surrogate pollutant to demonstrate an appropriate degree of control for a specified group of pollutants. For the purpose of identifying surrogates, pollutants have been grouped according to treatability classes; Table 8-2 presents the treatability classes identified for steam stripping.

For this example, the control authority may require compliance at Point A prior to dilution with nonprocess or un-regulated process wastewater or may require compliance at the point of discharge to the POTW by using the combined wastestream formula, if the additional dilution or non-regulated flows are known. However, cyanide should be monitored in-plant at point B on Figure 9-2, prior to commingling with non-cyanide-bearing wastewaters, unless Facility B can show a cyanide value other than non-detect at point A or the discharge point to the POTW.

Since Facility B performs steam stripping wastewater treatment on the subpart C wastewaters, Table 8-2 can be used as a guide to determine if surrogate pollutants may be appropriate for compliance monitoring. If the facility performs advanced biological treatment of its wastewater, treatability groups and surrogates identified in Table 8-1 could be used as a guide.

In Table 8-2, chloroform and toluene are both classified in the high strippability group, and both are listed as appropriate surrogate pollutants for that group. Acetone and isopropyl acetate are both classified in the medium strippability group, and acetone is listed as an appropriate surrogate pollutant for that group. If the use of surrogates is requested by a facility, control authorities may decide on the use and choice of surrogate pollutants on a facility-by-facility basis.

In this example, the choice of surrogate pollutant for the high strippability group will be based on the pollutant concentrations since two pollutants (chloroform and toluene) are listed as appropriate surrogates. Assuming the average pollutant concentrations are known to be 0.01 mg/L for chloroform and 0.1 mg/L for toluene, the permit writer would choose toluene as the surrogate pollutant. For the medium strippability group, the permit writer can base the choice of surrogate pollutant on the guidance provided in Table 8-2; thus, acetone would be chosen as the surrogate pollutant.

Therefore, Facility B would be required to routinely monitor for toluene and acetone at monitoring point A or the discharge point to the POTW, and for cyanide at monitoring point B, assuming cyanide is not detectable at point A.

9.2.5 Final Limits as They Would Appear in a Permit for Facility B

Table 9-8 presents the final limits as they would appear in a permit for Facility B on a concentration basis. If all cyanide-bearing waste streams are diverted to a cyanide destruction unit, self-monitoring for cyanide should be conducted after cyanide treatment and before dilution with other streams.

Table 9-8: Final Limits for Facility B

Pollutant	Effluent Limitations for Point A Monitoring Points		Effluent Limitation for Point B Monitoring Points	
	Maximum for any one day	Monthly Average	Maximum for any one day	Monthly Average
	(mg/L)	(mg/L)	(mg/L)	(mg/L)
Acetone	20.7	8.2	---	---
Chloroform	0.1	0.03	---	---
Cyanide	---	---	33.5	9.4
Isopropyl acetate	20.7	8.2	---	---
Toluene	0.3	0.2	---	---

If sufficient flow information is available, the permit writer may determine compliance concentrations at the discharge to the POTW point using the combined waste stream formula (CWF).

The limitations presented in Table 9-8 should have been complied with on or before September 21, 2001.

9.3 Case Study #3

Facility C is an existing multiple-subcategory, direct discharging pharmaceutical manufacturing facility which has on-site treatment and discharges to the Red River. The facility has submitted an application for a new NPDES permit.

9.3.1 General Site Description

The flow schematic for Facility C shows the flow from each operation, and is presented in Figure 9-3.

9.3.2 Relevant Information for Establishing Permit Limits

Table 9-9 summarizes relevant information for establishing permit limits for pollutants with effluent limitations guidelines.

Table 9-9: Information Needed to Establish Permit Limits for Case Study #3

What type of discharger is the facility?	Direct
Under which subparts do the facility's operations fall?	Subpart B and C
The facility is subject to which effluent limitations guidelines and standards?	BPT (40 CFR Part 439) BCT (40 CFR Part 439) BAT (40 CFR Part 439)
Is the dilution flow >25% of total flow?	Yes

9.3.3 Determining Permit Limits for Pollutants Regulated Under BPT

The 1998 final BPT effluent limitations guidelines revise the 1983 COD effluent limitations for subpart A, B, C, and D operations at direct discharging facilities. In 1983, EPA promulgated COD effluent limitations requiring 74% reduction in the long-term daily COD load in the raw (untreated) wastewater multiplied by a variability factor of 2.2. Under the 1998 revised BPT COD regulations, facilities must comply with the new COD concentration limitations or the 1983 BPT regulations, whichever is more stringent. This comparison would be based on the monthly average effluent limitations specified by the 1998 and 1983 guidelines. The BPT effluent limitations guidelines for BOD_5, TSS and pH have not been revised. The BPT effluent limitations for subpart E operations, established in the 1983 final rule, have also not been revised. The other conventional pollutants, fecal coliform and oil & grease, are not regulated by BPT for the pharmaceutical manufacturing point source category.

The effluent limitations guidelines are concentration-based and, as such, do not regulate wastewater flow. The permit writer must use a reasonable estimate of process wastewater discharge flow and the concentration-based limitations to develop mass-based limitations for the NPDES permit. Table 7-1 presents the maximum daily and monthly average BPT effluent limitations for subpart A, B, C, and D operations at direct discharging facilities.

The limitations for COD will be applied to the final effluent. An example calculation of the BPT maximum for any one day and monthly average COD limitations for this facility is shown in the following sections.

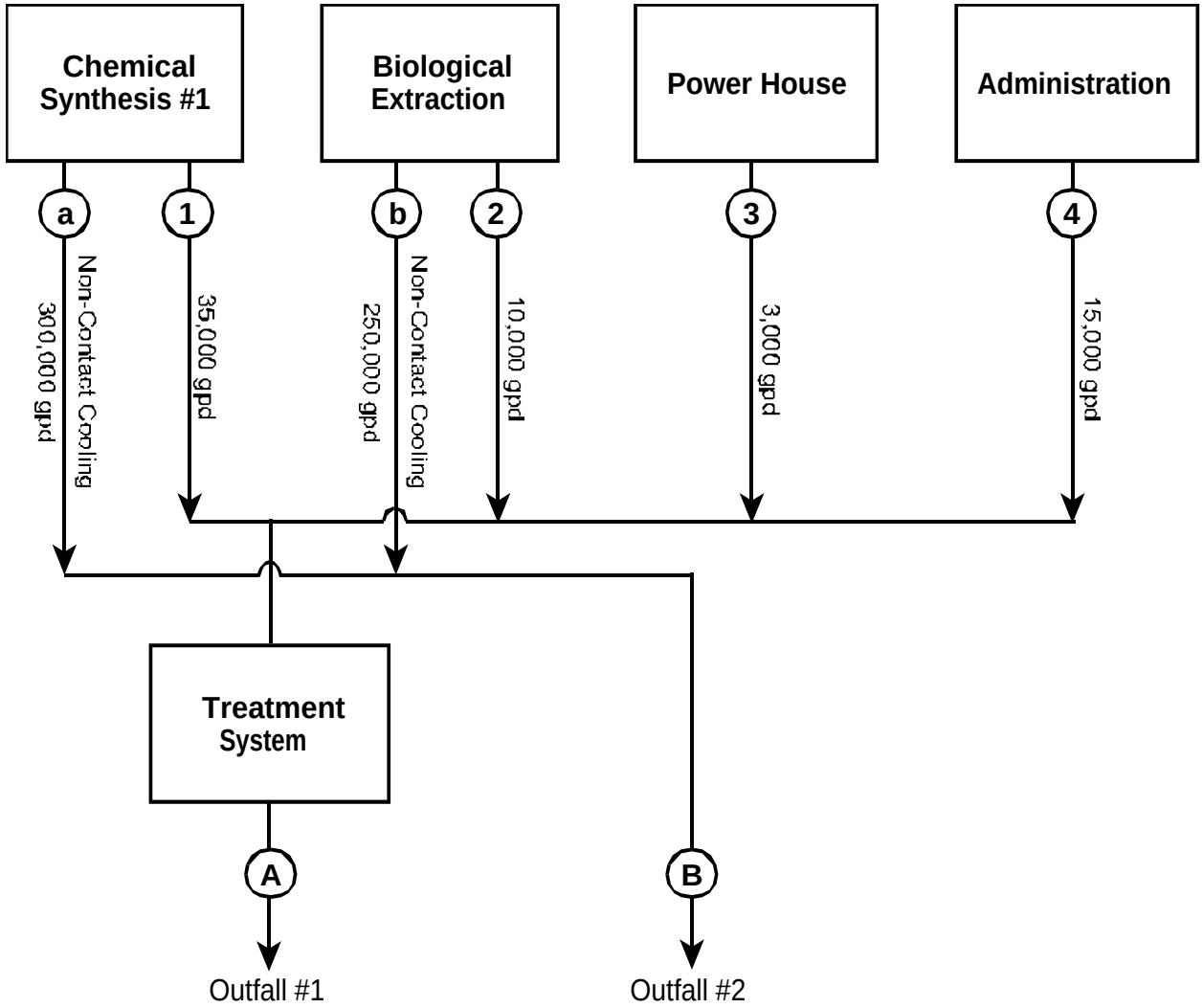

Figure 9-3: Flow Schematic for Facility C

Step 1. Determining Allowable Wastewater Discharge Flow

The first step in establishing permit limitations is to determine the types of wastestreams (i.e., regulated process, unregulated process, and dilute) at the facility. The flow breakdown for Facility C is shown in Table 9-10.

Table 9-10: Flow Breakdown for Facility C

Waste Stream	Flow (gal/day)	
Outfall #001		
1. Chemical synthesis	35,000	(Regulated, subpart C)
2. Biological extraction	10,000	(Regulated, subpart B)
3. Power house boiler blowdown	3,000	(Dilute or un-regulated)
4. Administration	15,000	(Dilute or un-regulated)
Total wastewater flow:	63,000	
Total regulated process flow:	45,000	
Total unregulated process flow:	0	
Total dilute flow:	18,000	
Outfall #002		
a. Chemical synthesis non-contact cooling	300,000	
b. Biological extraction non-contact cooling	250,000	
Total non-contact cooling:	550,000	
Total wastewater flow:	550,000	
Total regulated process flow:	0	
Total unregulated process flow:	0	
Total dilute flow:	550,000	

Streams 1 and 2 are considered regulated wastestreams because effluent limitations have been established for chemical synthesis operations (subpart C) and biological extraction operations (subpart B). Streams 3 and 4 are considered to be either dilution water or un-regulated streams. Depending on the pollutant loads for specific parameters, such as BOD_5, COD, or TSS, and the percent of the total flow, permit writers may consider streams 3 and 4 as un-regulated wastestreams instead of dilution. The non-contact cooling waters are not considered to be dilute streams since the discharge goes to a separate outfall. We have assumed the permit writer has sufficient information from the permit application to establish applicable permit limits for this separate outfall.

Using BPJ, the permit writer determines the annual average wastewater discharge flow for Facility C. Assuming the facility production and wastewater flow are not expected to change significantly during the permit term, the historical data provided by Facility C are used to establish the annual discharge flow. The discharge flow can then be used to develop mass-based effluent limitations. Only sources of "process wastewater discharge" and an allowance for up to 25 percent nonprocess wastewater should be considered. The allowable wastewater (WW) discharge flow used to establish the mass-based limitations is calculated as follows:

Process WW discharge = 45,000 gal/day
Allowable WW discharge = (0.25)Allowable WW discharge + Process WW discharge
(1 - 0.25) Allowable WW discharge = Process WW discharge
Allowable WW discharge = Process WW discharge / (0.75)
= 45,000 gal/day / (0.75)
= 60,000 gal/day

The allowable wastewater discharge flow used to establish the mass-based limitations can include (60,000 - 45,000) = 15,000 gallons per day of nonprocess wastewater. However, Facility C has 18,000 gallons per day of nonprocess wastewater (dilute). Since Facility C has greater than 25% nonprocess water, the maximum allowable wastewater discharge, 60,000 gal/day, will be used to establish mass-based effluent limitations.

For this example, 15,000 gallons per day of nonprocess water would be assigned pollutant mass limits and would be considered to be part of the regulated waste stream, not a dilution stream. However, the remaining 3,000 gallons per day of nonprocess (e.g. dilution) water greater than the 25% allowance would be considered to be dilution water and would not be assigned pollutant mass limits.

Table 7-1 presents the BPT effluent limitations for subpart A, B, C, and D operations at direct discharging facilities. Daily maximum limitations have not been promulgated for the pollutants BOD_5 and TSS for all subcategories, although EPA has promulgated daily maximum limitations on COD for subparts A, B, C, and D. Monthly average limitations for subpart E operations were promulgated in 1983 and are presented in 40 CFR 439.52.

To calculate the mass limits for the allowable nonprocess water, concentration limits for each subpart are applied to a percentage of the total allowable nonprocess water flow. This allowable nonprocess flow is divided between subparts based on the subpart A and C and subpart B and D process flow compared to the total process flow. The calculation for Facility C is shown below:

Subpart A and C process water flow	=	35,000 gal/day
Subpart B and D process water flow	=	10,000 gal/day
Total process water flow	=	45,000 gal/day

Allowable nonprocess water flow:

Subpart A and C concentration limits apply

$$= \frac{35{,}000 \text{ gal/day}}{45{,}000 \text{ gal/day}} \times 15{,}000 \text{ gal/day} = 11{,}667 \text{ gal/day}$$

Subpart B and D concentration limits apply

$$= \frac{10{,}000 \text{ gal/day}}{45{,}000 \text{ gal/day}} \times 15{,}000 \text{ gal/day} = 3{,}333 \text{ gal/day}$$

When calculating mass-based effluent limitations, 11,667 gallons per day of nonprocess water should be multiplied by the subpart A and C concentration limits, and 3,333 gallons per day of nonprocess water should be multiplied by the subpart B and D concentration limits.

Step 2. Determining the Use of Monthly Average Limitations vs. Percent Reduction for COD Limitations

Facility C must comply with either the revised COD concentration limitations or the previously promulgated COD limit requiring a reduction in the long-term average daily COD load in the raw (untreated) process wastewater of 74 percent multiplied by a variability factor of 2.2, whichever is more stringent. Permit authorities should compare the revised monthly average effluent limitations, which apply to subpart A, B, C and D operations, with the previously promulgated guidelines to determine which is more stringent. As mentioned previously, monthly average limitations for subpart E operations were not revised in the 1998 rule; the effluent limitations guidelines presented in 40 CFR 439.52, requiring a 74 percent reduction in the long-term daily COD load multiplied by a variability factor of 2.2, or 220 mg/L, whichever is greater, continue to apply.

Assuming subpart C operations at Facility C have an influent COD concentration of 1,000 mg/L in the wastewater treatment plant, a 74 percent reduction in the long-term average COD load multiplied by a variability factor of 2.2 would result in a final effluent discharge limitation of 572 mg/L. The revised COD limitations require a maximum monthly average of 856 mg/L for subpart A and C operations. Thus, the 74 percent reduction in COD is more stringent than the revised limits for COD. The monthly average limit for COD for the subpart C wastestream is 572 mg/L. This concentration of 572 mg/L would be converted to a mass-based limit in the NPDES permit. **[Note: the permit writer may need to request that the facility collect and supply raw subpart A and/or C process wastewater COD concentration data to conduct this analysis.]**

For the purpose of this case study, we assume subpart B operations at Facility C have an influent COD concentration of 700 mg/L in the wastewater treatment plant. However, the 1983 regulations stipulated that B, D, and E operations would not be required to maintain a monthly average COD effluent limitation of less than 220 mg/L. Since the September 21, 1998 regulation requires a COD monthly average of 86 mg/L or less, the 1998 regulation monthly average will always be more stringent. Thus, the monthly average limit for COD for subpart B wastestreams at Facility C is 86 mg/L.

The monthly average COD limitations for facility C would be calculated as shown below:

Subpart A and C limitations:

= (35,000 + 11,667) gal/day × 572 mg/L × [8.345×10^{-6} (L × lb)/(gal × mg)]

= 222.8 lbs/day

Subpart B and D concentration limits apply

= (10,000 + 3,333) gal/day × 86 mg/L × [8.345×10^{-6} (L × lb)/(gal × mg)]

= 9.6 lbs/day

Total mass limitation = 232.4 lbs/day

The monthly average effluent limitation for COD at Outfall #1 would be 232 lbs/day. This monthly average limitation is compared to the average of all daily mass discharge amounts in a calendar month to determine facility compliance.

Step 3. Determining Maximum Effluent Limitations for Any One Day

The permit writer must develop a daily maximum effluent limitation for subpart C flows. In Step 2, monthly average COD limits for Facility C's subpart C flows were calculated as 572 mg/L, using the 1983 COD limit because it was more stringent than the 1998 limit. The daily maximum effluent limitation should be developed from the 1983-based COD limits. However, the 1983 regulation does not specify maximum effluent limitations for any one day. The permit writer should therefore use the relationship between the 1998 daily maximum (1,675 mg/L) and the 1998 monthly average (856 mg/L) to calculate a 1983-based daily maximum for Facility C's subpart C flows.

The BPT COD maximum allowable discharge for any one day could be calculated as shown below:

Subpart A and C limitations:

= (35,000 + 11, 667) gal/day x 572 mg/L x [1, 675 mg/L/856 mg/L] x
[8.345×10^{-6} (L × lb)/(gal × mg)]

= 436 lbs/day

Facility C's subpart B wastestreams are subject to the 1998 BPT regulations for COD for both the monthly average and the maximum for any one day.

Subpart B and D limitations:

= (10,000 + 3,333) gal/day × 228 mg/L × [8.345×10^{-6} (L × lb)/(gal × mg)]
= 25.4 lbs/day

Total mass limitation = 461.4 lbs/day COD

Therefore, the maximum for any one day effluent limitation for COD at Outfall #1 would be 461 lbs/day.

9.3.4 Determining Permit Limits for Pollutants Regulated Under BAT

Tables 7-2 and 7-3 present the proposed maximum daily and monthly average BAT effluent limitations guidelines for subparts A and C, and subparts B and D, respectively. BAT for ammonia and the organic pollutants listed in these tables are applicable to the final effluent discharged to the waters of the United States.

Previously promulgated BAT limitations for cyanide are also presented in Table 7-2 and are applicable to subpart A and C operations. Compliance monitoring for cyanide should occur immediately after cyanide destruction, before commingling cyanide-bearing wastestreams with noncyanide-bearing wastestreams, unless a facility can demonstrate that cyanide is detectable at the end-of-pipe sampling point and applicable information exists to use the end-of-pipe monitoring results to determine compliance. In-plant monitoring is required at those facilities unable to detect cyanide at the end-of-pipe monitoring point.

We will assume that Facility C has provided the permit writer with an accurate characterization of its process wastestreams by means available such as solvent use and disposition data, and chemical analysis of each stream. Permit writers should establish permit limitations and require compliance monitoring for each regulated pollutant generated or used at a pharmaceutical manufacturing facility. Routine compliance monitoring is not required for regulated pollutants not generated or used at a facility. Facilities should make a determination that regulated pollutants are not generated or used based on a review of all raw materials used, and an assessment of all chemical processes used, and consideration of resulting products and by-products. The determination that a regulated pollutant is not generated or used should be confirmed by annual chemical analyses of wastewater from each monitoring location, and these analyses must be submitted to the permit writer. Such confirmation is provided if the pollutant is not-detected above the ML of an EPA-approved analytical method.

Table 9-11 presents a summary of the regulated pollutants expected to be found in this facility's waste streams:

Table 9-11: Regulated Pollutants Found in the Wastewater of Facility C

Stream	Subpart	Flow (gal/day)	Pollutant
1	C	35,000	Methylene chloride, tetrahydrofuran, acetone, methanol, toluene, COD
2	B	10,000	Methanol, tetrahydrofuran, COD
3	N/A	3,000	No BAT pollutants
4	N/A	15,000	No BAT pollutants

Based on the above data, permit writers would use reasonable estimates of the process wastewater discharge flow, allowing for up to 25% nonprocess wastewater, and the concentration-based standards in Tables 7-3 and 7-4 to develop limitations for methylene chloride, tetrahydrofuran, acetone, methanol, and toluene in the NPDES permit. Permit limitations would also be established for COD under BAT.

Step 1. Determining Maximum Limitations for Any One Day for Organic Pollutants and COD under BAT

As shown in Table 7-2, methylene chloride, acetone, methanol, tetrahydrofuran and toluene have the following maximum daily limitations for subparts A and C.

Methylene chloride:	0.9 mg/L
Acetone:	0.5 mg/L
Methanol:	10.0 mg/L
Tetrahydrofuran:	8.4 mg/L
Toluene:	0.06 mg/L

Methylene chloride, acetone and toluene are present only in waste streams in which organic pollutants are regulated (i.e. subpart A and C waste streams). The allowable wastewater flow for Facility C is calculated as shown below.

Process wastewater flow (regulated subpart A and C):

= Stream 1 (subpart C) = 35,000 gal/day

Allowable wastewater flow:

= Process wastewater flow/(0.75)
= 35,000 gal/day/(0.75)
= 46,667 gal/day

Total nonprocess wastewater flow, including unregulated process wastewater (subpart B, D, and E operations):

= Stream 2 (subpart B) + Stream 3 (dilution) + Stream 4 (dilution)
= 10,000 + 3,000 + 15,000 = 28,000 gal/day

The allowable wastewater flow for calculating BAT mass-based effluent limitations is 46,667 gal/day. Facility C total flow of 63,000 gal/day exceeds this allowance, therefore the allowable wastewater flow (46,667 gal/day) will be used to calculate effluent limitations.

The daily maximum mass-based effluent limitation for acetone is calculated as follows:

$L_m = L_c \times F \times k_1$
= 0.5 mg/L × 46,667 gal/day × [8.345×10^{-6} (L × lb)/(gal × mg)]
= 0.19 lbs/day

The total facility maximum daily discharge limitation for acetone is 0.19 lbs/day. The maximum daily effluent limitations for methylene chloride and toluene can be calculated in a similar manner.

Methanol and tetrahydrofuran are both present in stream 1, a regulated waste stream for organic pollutants, and stream 2, an unregulated waste stream for organic pollutants. Permit writers use BPJ to set unregulated waste stream limitations and calculate maximum daily discharge limitations using the combined wastestream formula. Permit writers may calculate the maximum daily discharge limitations using the combined waste stream formula (CWF) shown below:

$$M_T = \left[\sum_{i=1}^{N} M_i\right] \times \left[\frac{F_T - F_D}{\sum_{i=1}^{N} F_i}\right]$$

where:

M_T	=	Alternative mass limit for the pollutant in the combined wastestream (mass per day).
M_i	=	Treatment standard for the pollutant in the regulated stream i (mass per day)
F_i	=	Average daily flow (at least 30 day average) of the regulated stream i
F_D	=	Average daily flow (at least 30 day average) of dilute wastestream(s) entering the combined treatment system
F_T	=	Average daily flow (at least 30 day average) through the combined treatment facility (including regulated, unregulated, and dilute wastestreams)
N	=	Total Number of regulated streams

In this example, the maximum one day effluent limitation for tetrahydrofuran is calculated as follows:

M_1	=	Mass limit of tetrahydrofuran in stream 1 (subpart C)
	=	8.4 mg/L × 35,000 gal/day × [8.345×10^{-6} (L × lb)/(gal × mg)]
	=	2.5 lbs/day
M_{NP}	=	Mass limit of tetrahydrofuran in nonprocess water stream
	=	8.4 mg/L × 11,667 gal/day × [8.345×10^{-6} (L × lb)/(gal × mg)]
	=	0.82 lbs/day
F_T	=	Total flow = 63,000
F_D	=	Dilution flow = 3,000 (excluding 25% allowable nonprocess water flow)
F_1	=	Flow in stream 1 = 35,000 gal/day
F_{NP}	=	Nonprocess water flow = 11,667 gal/day
$\sum M_i$	=	3.3 lbs/day
$\sum F_i$	=	46,667 gal/day
M_T	=	$3.3 \text{ lbs/day} \times \frac{[63{,}000 - 3{,}000] \text{ gal/day}}{46{,}667 \text{ gal/day}} = 4.2 \text{ lbs/day}$

The maximum one day effluent limitation for tetrahydrofuran is equal to 4.2 lbs/day. The maximum one-day effluent limitation for methanol can be calculated in a similar manner.

The maximum one day effluent limitation for COD under BAT can be calculated like the maximum one day effluent limitation for acetone. The resulting daily maximum mass-based effluent limitation is 677 lbs/day. However, in setting permit limits for this facility, the limit calculated under BPT based on the 74% reduction for the subpart A and C wastewater and the September 21, 1998 promulgated limit of 86 mg/L for the subpart B and D wastewater is 461 lb/day, which is more stringent than the monthly average of 677 lb/day (based on the September 21, 1998 BAT limits). So, in this instance, the BPT limit of 461 lbs/day is controlling and forms the basis of the permit limits.

Step 2. Determining Monthly Average Limitations for Organic Pollutants and COD under BAT

The following monthly average limitations, listed in Table 7-2, apply for Facility C pollutants methylene chloride, acetone, methanol, tetrahydrofuran and toluene:

Methylene chloride:	0.3 mg/L
Acetone:	0.2 mg/L
Methanol:	4.1 mg/L
Tetrahydrofuran:	2.6 mg/L
Toluene:	0.02 mg/L

Methylene chloride, acetone and toluene are present only in waste streams in which organic pollutants are regulated (i.e. subpart A and C waste streams). The concentration based limitations for these pollutants can be converted to monthly average mass-based limitations by the same methodology used in

calculating maximum limitations for any one day. Below is the calculation for monthly average limitations for toluene.

$L_m = L_c \times F \times k_1$
$= 0.02 \text{ mg/L} \times 46{,}667 \text{ gal/day} \times [8.345 \times 10^{-6} \text{ (L} \times \text{lb)/(gal} \times \text{mg)}]$
$= 0.008 \text{ lbs/day}$

The total facility monthly average discharge limitation for toluene is 0.008 lbs/day. The monthly average limitation is compared to the average of all daily mass discharge amounts in a calendar month to determine facility compliance. The maximum daily effluent limitations for methylene chloride and acetone can be calculated in a similar manner.

Methanol and tetrahydrofuran are both present in stream 1, a regulated waste stream for organic pollutants, and stream 2, an unregulated waste stream for organic pollutants. Permit writers use BPJ to set unregulated waste stream limitations. Permit writers may calculate the monthly average discharge limitations using the combined waste stream formula (CWF):

In this example, the mass-based monthly average effluent limitation for methanol is calculated as follows:

M_1 = Mass limit of methanol in stream 1 (subpart C)
$= 4.1 \text{ mg/L} \times 35{,}000 \text{ gal/day} \times [8.345 \times 10^{-6} \text{ (L} \times \text{lb)/(gal} \times \text{mg)}]$
$= 1.2 \text{ lbs/day}$
M_{NP} = Mass limit of methanol in nonprocess water allowance stream
$= 4.1 \text{ mg/L} \times 11{,}667 \text{ gal/day} \times [8.345 \times 10^{-6} \text{ (L} \times \text{lb)/(gal} \times \text{mg)}]$
$= 0.40 \text{ lbs/day}$
F_T = Total flow = 63,000
F_D = Dilution flow = 3,000 (excluding 25% allowable nonprocess water flow)
F_1 = Flow in stream 1 = 35,000 gal/day
F_{NP} = Nonprocess water allowance flow = 11,667 gal/day
$\sum M_i$ = 1.6 lbs/day
$\sum F_i$ = 46,667 gal/day

$$M_T = 1.6 \text{ lbs/day} \times \frac{[63{,}000 - 3{,}000] \text{ gal/day}}{46{,}667 \text{ gal/day}} = 2.1 \text{ lbs/day}$$

The total facility monthly average effluent limitation for methanol is 2.1 lbs/day. The monthly average limitation is compared to the average of all daily mass discharge amounts in a calendar month to determine facility compliance. The monthly average effluent limitation for tetrahydrofuran can be calculated in a similar manner.

The monthly average effluent limitations for COD can be calculated like the monthly average COD limitation under BPT. In fact, the promulgated BPT and BAT monthly average effluent limitations guidelines for COD concentrations are the same. However, in setting permit limits for this facility, the limit calculated under BPT based on the 74% reduction for the subpart A and C wastewater and the September 21, 1998 promulgated limit of 86 mg/L for the subpart B and D wastewater is 232 lb/day, which is more stringent than the monthly average of 343 lb/day (based on the September 21, 1998 BAT limits). So, in this instance, the BPT limit of 232 lbs/day is controlling and forms the basis of the permit limits.

9.3.5 Final Limits as They Would Appear in a Permit for Facility C

Table 9-12 presents the final limits as they would appear in a permit for Facility C on a mass-basis. Permit writers can choose to show limits on a concentration-basis, in addition to the mass-based limits.

Table 9-12: Final Limits for Facility C

Pollutant or Pollutant Property [a]	Effluent Limitations for In-Plant and EOP Monitoring Points		
	Maximum for Any One Day (lb/day)	Monthly Average (lb/day)	Monitoring Point
Chemical Oxygen Demand (COD)	461	232	EOP
Acetone	0.19	0.08	EOP
Methanol	5.0	2.1	EOP
Methylene Chloride	0.35	0.12	EOP
Tetrahydrofuran	4.2	1.3	EOP
Toluene	0.02	0.008	EOP

[a] pH, BOD_5, and TSS limits are not shown here since they have not been changed by the September 21, 1998 promulgated rule. These limits will be calculated as they have been in the past.

Note: A facility must be able to show compliance with mass-based limitations at the end-of-pipe monitoring point. If excessive dilution waters are mixed with regulated process wastewaters prior to the end-of-pipe monitoring point, it is possible that compliance would require measurement of a pollutant below its detection level. If that were to occur, the permit authority should require monitoring at a point prior to the addition of dilution flow.

In this example, the required concentration for each monitored organic pollutant to demonstrate compliance with the mass-based limitations is above each pollutant's detection limit.

The limitations presented in Table 9-12 would be effective on November 20, 1998 or upon reissuance of the current permit, whichever is later.

9.4 Case Study #4

Facility D is a direct discharging manufacturing facility with operations in two industrial categories. This facility manufactures pharmaceuticals as well as bulk organic chemicals.

Case Study #4 highlights:

1. BPT/BAT for a multiple industrial category facility (OCPSF and Pharmaceutical Manufacturing).

9.4.1 General Site Description

The flow schematic for Facility D shows the flow from each operation and is presented in Figure 9-4.

9.4.2 Relevant Information for Establishing Permit Limits

Table 9-13 summarizes the relevant information from the permit application needed to calculate discharge limits.

Table 9-13: Information Needed to Establish Permit Limits for Case Study #4

What type of discharger is the facility?	Direct (pharmaceutical and OCPSF wastewater)
Under which subparts do the facility's operations fall?	Subpart A and C - pharmaceuticals
The facility is subject to which effluent limitations guidelines and standards?	BPT (40 CFR Part 439) BCT (40 CFR Part 439) BAT (40 CFR Part 439) OCPSF (40 CFR Part 414)

9.4.3 Determining Permit Limits for Pollutants Regulated Under BPT

The 1998 final BPT effluent limitations guidelines revise the 1983 COD effluent limitations for subpart A, B, C, and D direct discharging facilities. In 1983, EPA promulgated COD limits requiring 74% reduction in the long-term daily COD load of the raw (untreated) wastewater multiplied by a variability factor of 2.2. Under the 1998 revised BPT COD regulations, facilities must comply with the new COD concentration limitations or the1983 BPT regulations, whichever is more stringent. This comparison is based on the monthly average effluent limitations specified by the 1998 and 1983 limitations. As described in Case Study 1, the BOD_5, TSS and pH effluent limits have not been amended, and other conventional pollutants are not regulated by BPT for the pharmaceutical manufacturing point source category.

The effluent limitations guidelines are concentration-based and, as such, do not regulate wastewater flow. The permit writer must use a reasonable estimate of process wastewater discharge flow and the concentration-based limitations to develop mass-based limitations for the NPDES permit. Table 7-1 presents the maximum daily and monthly average BPT effluent limitations for subpart A, B, C, and D direct discharging facilities.

The limitations for COD will be applied to the final effluent at monitoring point B in Figure 9-4. An example calculation of the BPT maximum day and monthly average COD limitations for this facility follows.

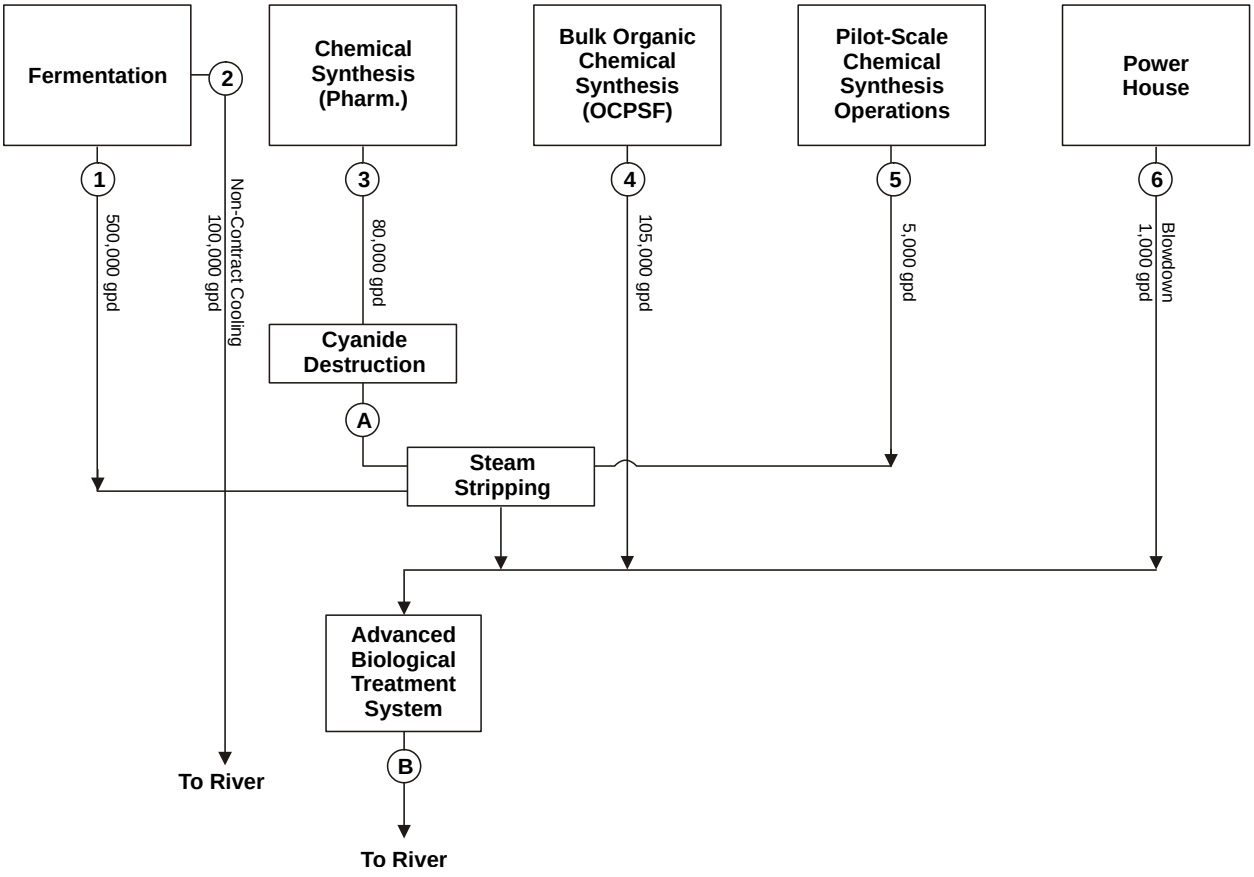

Figure 9-4: Flow Schematic for Facility D

Step 1. Determining Allowable Wastewater Discharge Flow

The first step in establishing permit limitations is to determine the types of wastestreams present. The flow breakdown for facility D is shown in Table 9-14.

Table 9-14: Flow Breakdown for Facility D

Waste Stream	Flow (gal/day)	
1. Fermentation	500,000	(Regulated, subpart A)
3. Chemical Synthesis	80,000	(Regulated, subpart C)
4. Bulk Organic Chemicals	105,000	(Regulated, OCPSF)
5. Pilot-Scale Chemical Synthesis	5,000	(Regulated, subpart C)
6. Power House Boiler Blowdown	1,000	(Dilute)
Total Wastewater Flow:	691,000	
Total Regulated Process:	690,000	
Total Unregulated Process:	0	
Total Dilute:	1,000	
2. Noncontact Cooling Water	100,000	(Dilute)

Streams 1, 3, 4, and 5 are considered regulated waste streams as effluent limitations have been established for fermentation operations (subpart A), chemical synthesis operations (subpart C), and OCPSF bulk organic chemical operations. Pharmaceutical effluent limitations apply to facilities handling >50% pharmaceutical process wastewater. Facility E handles [(500,000 + 80,000 + 5,000)/690,000] × 100% = 84% pharmaceutical wastewaters.

Using BPJ, Facility D's annual average wastewater discharge flow can be established. Assuming the facility production and wastewater flow is not expected to change significantly during the permit term, the historical data provided by Facility D will be used to establish the annual discharge flow used to develop mass-based effluent limitations. Only sources of "process wastewater discharge" and an allowance for up to 25 percent nonprocess wastewater should be considered. The allowable wastewater (WW) discharge flow used to establish the mass-based limitations is calculated as follows:

Process WW discharge = 690,000 gal/day

Allowable WW discharge = (0.25)Allowable WW discharge + Process WW discharge

(1 - 0.25) Allowable WW discharge = Process WW discharge

Allowable WW discharge = Process WW discharge / (0.75)
= 690,000 gal/day / (0.75)
= 920,000 gal/day

The allowable wastewater discharge flow used to establish the COD mass-based limitations can include (920,000 - 690,000) = 230,000 gallons per day of nonprocess wastewater. However, Facility D only has 1,000 gallons per day of nonprocess wastewater (stream 6), and therefore, the annual average wastewater discharge flow is determined to be (690,000 + 1,000) = 691,000 gallons per day.

For this example, stream 6 would be assigned a mass limit and would be considered to be a regulated waste stream, not a dilution stream. However, any nonprocess (e.g. dilution) water greater than the 25% allowance would be considered to be a dilution stream and would not be assigned a mass limit.

To calculate the mass limits for stream 6, concentration limits for each subpart are applied to a percentage of the total stream 6 flow. Facility D only has subpart A and C operations, and therefore, subpart A and C effluent limitations will be applied to stream 6.

Table 7-1 presents the proposed maximum daily and monthly average BPT effluent limitations for subpart A, B, C, and D operations. 40 CFR 414.71 presents the maximum daily and monthly average BPT effluent limitations for bulk organic chemical OCPSF wastewaters.

Step 2. Determining the Use of Monthly Average Limitations vs. Percent Reduction for COD Limitations

Facility D must comply with either the revised COD concentration limitations or the previously promulgated COD limit requiring a reduction in the long-term average daily COD load in the raw (untreated) process wastewater of 74 percent multiplied by a variability factor of 2.2, whichever is more stringent. Permit authorities should compare the revised monthly average effluent limitations, which apply to subpart A, B, C and D operations, with the previously promulgated guidelines to determine which is more stringent. As mentioned previously, monthly average limitations for subpart E operations were not revised in the 1998 final rule; the effluent limitations guidelines presented in 40 CFR 439.52, requiring a 74 percent reduction in the long-term daily COD load multiplied by a variability factor of 2.2, or 220 mg/L, whichever is greater, continue to apply.

Assuming subpart A and C operations at Facility E have an influent COD concentration of 2,500 mg/L in the wastewater treatment plant, a 74 percent reduction in the long-term daily COD load multiplied by a variability factor of 2.2 would result in a final effluent discharge limitation of 1,430 mg/L. The revised COD limitations require a maximum monthly average of 856 mg/L for subpart A and C operations. The revised COD limitations of 856 mg/L are more stringent. Therefore, Facility D must comply with the mass-based limitations derived from the concentration-based COD limitations promulgated in 1998.

Step 3. Determining Maximum COD Effluent Limitation for Any One Day

COD is not regulated in wastewater from chemical synthesis operations at OCPSF facilities (40 CFR Part 414). In cases where OCPSF wastewaters are combined with pharmaceutical wastewaters and treated in a central unit, the maximum daily and monthly average limitations for COD can be calculated by determining the mass discharge allowance using the CWF shown below:

$$M_T = \left[\sum_{i=1}^{N} M_i\right] \times \left[\frac{F_T - F_D}{\sum_{i=1}^{N} F_i}\right]$$

where:

	M_T	=	Alternative mass limit for the pollutant in the combined wastestream (mass per day).
	M_i	=	Treatment standard for the pollutant in the regulated stream i (mass per day)
	F_i	=	Average daily flow (at least 30 day average) of the regulated stream i
	F_D	=	Average daily flow (at least 30 day average) of dilute wastestream(s) entering the combined treatment system
	F_T	=	Average daily flow (at least 30 day average) through the combined treatment facility (including regulated, unregulated, and dilute wastestreams)
	N	=	Total Number of regulated streams

The OCPSF waste stream (stream 4) is considered to be unregulated for COD; permit writers can use the CWF for calculating the mass-based effluent limitation applied at the end-of-pipe for Facility D.

In this example, the previously listed variables are calculated as follows:

$$M_T = \frac{8{,}191 \text{ lbs}}{\text{day}} \times \left[\frac{691{,}000 \text{ gpd} - 0 \text{ gpd}}{586{,}000 \text{ gpd}}\right] = 9{,}659 \text{ lbs/day COD}$$

M_1 = Mass limit for COD in stream 1 (subpart A)
M_1 = 1,675 mg/L × 500,000 gal/day × [8.345×10^{-6} (L × lb)/(gal × mg)]
= 6,989 lbs/day
M_3 = Mass limit for COD in stream 3 (subpart C)
M_3 = 1,675 mg/L × 80,000 gal/day ×[8.345×10^{-6} (L × lb)/(gal × mg)]
= 1,118 lbs/day
M_5 = Mass limit for COD in stream 5 (subpart C)
M_5 = 1,675 mg/L × 5,000 gal/day × [8.345×10^{-6} (L × lb)/(gal × mg)]
= 70 lbs/day
M_6 = Mass limit for allowable nonprocess water
M_6 = 1,675 mg/L × 1,000 gal/day × [8.345×10^{-6} (L × lb)/(gal × mg)]
= 14 lbs/day
F_T = Total flow = 691,000 gal/day
F_D = Dilution flow = 0 (all dilution water is included in the allowable nonprocess water flow)
F_1 = Flow in stream 1 = 500,000 gal/day
F_3 = Flow in stream 3 = 80,000 gal/day
F_5 = Flow in stream 5 = 5,000 gal/day
F_6 = Flow in stream 6 = 1,000 gal/day
$\sum Mi$ = 8,191 lbs/day
$\sum Fi$ = 586,000 gal/day

Total facility discharge limitation for any one day for COD is 9,659 lbs/day.

Step 4. Determining Monthly Average Effluent Limitations

Monthly average limitations for COD can be calculated in a similar manner as the maximum daily limitations. We will use the CWF from the previous section to determine mass-based COD monthly average limitations as shown below:

$$M_T = \frac{4{,}186 \text{ lbs}}{\text{day}} \times \left[\frac{691{,}000 \text{ gpd} - 0 \text{ gpd}}{586{,}000 \text{ gpd}}\right] = 4{,}936 \text{ lbs/day COD}$$

M_1 = 856 mg/L × 500,000 gal/day × [8.345×10^{-6} (L × lb)/(gal × mg)]
= 3,572 lbs/day
M_3 = 856 mg/L × 80,000 gal/day × [8.345×10^{-6} (L × lb)/(gal × mg)]
= 571 lbs/day
M_5 = 856 mg/L × 5,000 gal/day × [8.345×10^{-6} (L × lb)/(gal × mg)]
= 36 lbs/day
M_6 = 856 mg/L × 1,000 gal/day × [8.345×10^{-6} (L × lb)/(gal × mg)]
= 7 lbs/day
F_T = Total flow = 691,000 gal/day
F_D = Dilution flow = 0 (dilute included in nonprocess water allowance)
$\sum Mi$ = 4,186 lbs/day
$\sum Fi$ = 586,000 gal/day

Total facility monthly average discharge limitation for COD is 4,936 lbs/day. This monthly average limitation is compared to the average of all the daily mass discharges in a calendar month to determine facility compliance.

9.4.4 Determining Permit Limits for Pollutants Regulated Under BAT

Tables 7-2 and 7-3 present the proposed maximum daily and monthly average BAT effluent limitations guidelines for subparts A and C, and subparts B and D, respectively.

We will assume that Facility D has provided the permit writer with an accurate characterization of its process wastestreams by means available such as solvent use and disposition data, and chemical analysis of each stream. Permit writers should establish permit limitations and require compliance monitoring for each regulated pollutant generated or used at a pharmaceutical manufacturing facility. Routine compliance monitoring is not required for regulated pollutants not generated or used at a facility. Facilities should make a determination that regulated pollutants are not generated or used based on a review of all raw materials used, and an assessment of all chemical processes used, and consideration of resulting products and by-products. The determination that a regulated pollutant is not generated or used should be confirmed by annual chemical analyses of wastewater from each monitoring location, and these analyses must be submitted to the permit writer. Such confirmation is provided if the pollutant is not-detected above the ML of an EPA-approved analytical method.

Table 9-15 presents a summary of the regulated pollutants expected to be found in this facility's wastestreams:

Table 9-15: Regulated Pollutants Found in the Wastewater at Facility D

Stream	Subpart	Flow (gal/day)	Pollutant	Concentration (mg/L)
1	A	500,000	Methylene chloride Methanol Toluene	100 1,000 700
2	N/A	100,000	None	None
3	C	80,000	Cyanide Acetonitrile Methylene chloride Methanol	50 500 200 100
4	OCPSF	105,000	Acetonitrile Methylene chloride	100 150
5	C	5,000	Methanol	250
6	N/A	1,000	None	None

Based on the above data, permit limitations would be established for acetonitrile, cyanide, methanol, methylene chloride, and toluene. The limitations for all organic pollutants listed above except cyanide would be applied to the final effluent at monitoring point B.

BAT effluent limitations for cyanide should be applied in-plant before commingling with non-cyanide bearing wastewaters, unless a facility can show cyanide is detectable at the end-of-pipe monitoring point. The cyanide standards are applicable to wastewaters from subpart A and C operations that contain cyanide. Therefore, the concentration-based limitations for cyanide will apply to process wastestream 3 at point A, prior to dilution or mixing with any non-cyanide bearing wastewater.

Step 1. Determining BAT Maximum Effluent Limitations for Any One Day

The following maximum effluent limitations for any one day apply to pharmaceutical subpart A and C operations:

Methylene chloride:	0.9 mg/L
Methanol:	10.0 mg/L
Toluene:	0.06 mg/L
Cyanide:	33.5 mg/L
Acetonitrile:	25.0 mg/L

For our example, the allowable mass discharge of methylene chloride for any one day will be calculated. Methylene chloride is present and regulated in both pharmaceutical and OCPSF bulk chemicals wastewater. We are assuming Facility D produces more than five million pounds of OCPSF chemicals per year, and have applied the methylene chloride daily limitation for OCPSF wastewaters listed in 40 CFR 414.91 as shown below. The maximum daily limitations for methylene chloride for pharmaceutical subparts A and C is 0.9 mg/L and for OCPSF wastewater is 89 μg/L . Since monitoring points for organic pollutants under BAT are at end-of-pipe locations and all process wastewaters will be combined at this location, a mass discharge limitation for each waste stream will be determined.

Stream 1 (subpart A): 0.9 mg/L × 500,000 gal/day × [8.345 × 10^{-6} (L × lb)/(gal × mg)]
= 3.8 lbs/day

Stream 3 (subpart C): 0.9 mg/L × 80,000 gal/day × [8.345 × 10^{-6} (L × lb)/(gal × mg)]
= 0.6 lbs/day

Stream 4 (OCPSF): 89 μg/L × 105,000 gal/day ×[8.345 × 10^{-9} (L × lb)/(gal × μg)]
= 0.078 lbs/day

Stream 5 (subpart C): 0.9 mg/L × 5,000 gal/day × [8.345 × 10^{-6} (L × lb)/(gal × mg)]
= 0.038 lbs/day

Stream 6 (Nonprocess Wastewater Allowance): 0.9 mg/L × 1,000 gal/day × [8.345 × 10^{-6} (L × lb)/(gal × mg)]
= 0.0075 lbs/day

Total = 4.5 lbs/day

The total maximum daily discharge for methylene chloride is 4.5 lbs/day.

The maximum daily effluent limitations for methanol, toluene, and acetonitrile can be calculated in a similar manner. The maximum daily effluent limitation for cyanide is calculated using the flow for stream 3 only.

Step 2. Determining BAT Monthly Average Limitations

Monthly average limitations for organic pollutants, ammonia and cyanide can be calculated using the same method used to determine the mass-based maximum daily effluent limitations. The following monthly average effluent limitations apply to pharmaceutical subpart A and C operations:

Methylene chloride:	0.3 mg/L
Methanol:	4.1 mg/L
Toluene:	0.02 mg/L
Cyanide:	9.4 mg/L
Acetonitrile:	10.2 mg/L

The monthly average effluent limitations for OCPSF operations is listed in 40 CFR 414.91. The following calculations can be performed to determine the mass-based monthly average effluent limitations for methylene chloride.

Pharmaceutical subparts A and C allowable discharge:

$$0.3 \text{ mg/L} \times (500{,}000 \text{ gal/day} + 80{,}000 \text{ gal/day} + 5{,}000 \text{ gal/day} + 1{,}000 \text{ gal/day}) \times [8.345 \times 10^{-6} \text{ (L} \times \text{lb)/(gal} \times \text{mg)}] = 1.5 \text{ lbs/day}$$

OCPSF Bulk Chemicals Subcategory:

$$40 \ \mu\text{g/L} \times 105{,}000 \text{ gal/day} \times [8.345 \times 10^{-9} \text{ (L} \times \text{lb)/(gal} \times \mu\text{g)}] = 0.035 \text{ lbs/day}$$

Total = 1.5 lbs/day

The monthly average discharge limitation for methylene chloride is 1.5 lbs/day. The monthly average limitations for methanol, toluene, and acetonitrile can be calculated in a similar manner. The monthly average limitation for cyanide is calculated using the flow for stream 3 only. The monthly average limitations calculated as shown above are compared to the average of all the daily mass discharge amounts for a pollutant during a calendar month to determine facility compliance.

Step 3. Determining Compliance Monitoring for BAT Pollutants

Facilities discharging more than one regulated pollutant may request to monitor for a single surrogate pollutant to demonstrate an appropriate degree of control for a specified group of pollutants. For the purpose of identifying surrogates, pollutants have been grouped according to treatability classes; Tables 8-1 and 8-2 present the treatability classes identified for advanced biological treatment and steam stripping, respectively.

Facility D wastewater treatment is advanced biological treatment, and we can use Table 8-1 as a guide to determine if surrogate pollutants may be appropriate for compliance monitoring. None of the pollutants at Facility D are classified in the same treatability class, however, if a facility requests to use surrogate pollutants, a permit writer may decide on a facility-by-facility basis whether surrogate pollutants are appropriate and which pollutant may be used as a surrogate. For this example, we did not identify any appropriate surrogates, therefore Facility D should routinely monitor for all regulated pollutants generated or used on-site.

For this example, Facility D should perform compliance monitoring at Point B in Figure 9-4, directly after the wastewater treatment facility for all pollutants except cyanide, unless cyanide is detectable at the end-of-pipe monitoring point. If cyanide is not detectable at the end-of-pipe monitoring point, compliance monitoring should occur in-plant at Point A in Figure 9-4.

9.4.5 Final Limits as They Would Appear in a Permit for Facility D

Table 9-16 presents the final limits as they would appear in a permit for Facility D. Permit writers can choose to apply cyanide limits at end-of-pipe, provided that the cyanide value can be detected.

The limitations presented in Table 9-16 were effective on November 20, 1998 or upon reissuance of the current permit, whichever is later.

Table 9-16: Final Limits for Facility D

Pollutant or Pollutant Property [a]	Effluent Limitation for End-of-Pipe Monitoring Points		Effluent Limitation for In-Plant Monitoring Points	
	Maximum for any one day (lb/day)	Monthly Average (lb/day)	Maximum for any one day (lb/day)	Monthly Average (lb/day)
COD (BPT and BAT)	9,659	4,936	---	---
Cyanide	---	---	22.4	6.3
Acetonitrile	144	59	---	---
Methanol	58	24	---	---
Methylene Chloride	4.5	1.5	---	---
Toluene	0.36	0.12	---	---

[a] pH, BOD_5, and TSS limits are not shown here since they have not been changed by the September 21, 1998 promulgated rule. These limits would be calculated as they have been in the past.