Permit Guidance Document: Pharmaceutical Manufacturing Point Source Category (40 CFR Part 439)

January 2006

Permit Guidance Document: Pharmaceutical Manufacturing Point Source Category (40 CFR Part 439)

U.S. Environmental Protection Agency
Office of Water
Engineering and Analysis Division
1200 Pennsylvania Avenue, NW (4303T)
Washington, DC 20460

EPA 821-F-05-006

January 2006

Disclaimer

The discussion in this document is intended solely as guidance. The statutory provisions and regulations of the U.S. Environmental Protection Agency (EPA) described in this document contain legally binding requirements. This document is not a regulation itself, nor does it change or substitute for those provisions and regulations. Thus, it does not impose legally binding requirements on EPA, States or the regulated community. This guidance does not confer legal rights or impose legal obligations upon any member of the public.

While EPA has made every effort to ensure the accuracy of the discussion in this guidance, the obligations of the regulated community are determined by statutes, regulations or other legally binding requirements. In the event of a conflict between the discussion in this document and any statute or regulation, this document would not be controlling.

The general descriptions provided here may not apply to particular situations based upon the circumstances. Interested parties are free to raise questions and objections about the substance of this guidance and the appropriateness of the application of this guidance to a particular situation. EPA and other decision makers retain the discretion to adopt approaches on a case-by-case basis that differ from those described in this guidance where appropriate.

Mention of trade names or commercial products does not constitute an endorsement or recommendation for their use.

This document may be revised periodically without public notice. EPA welcomes public input on this document at any time.

Executive Summary

On September 21, 1998, the U.S. Environmental Protection Agency (EPA) promulgated revised regulations for the pharmaceutical industry to control both effluent discharges and air emissions. The purpose of this guidance document is to help permit writers and pretreatment coordinators develop appropriate National Pollutant Discharge Elimination System (NPDES) permits and pretreatment requirements for pharmaceutical facilities with the following types of operations: fermentation, extraction, chemical synthesis, mixing, compounding and formulating and research. For an overview of the NPDES and National Pretreatment Programs, refer to the *U.S. EPA NPDES Permit Writer's Manual* (EPA-833-B-96-003) as well as the *Industrial User Permitting Guidance Manual* (EPA-833/R-89-001).

Contents

Tables

Figures

1. Introduction

On September 21, 1998, the U.S. Environmental Protection Agency (EPA) promulgated final effluent limitations guidelines and standards under the Clean Water Act (CWA). These regulations amended existing effluent limitations guidelines and standards codified at 40 Code of Federal Regulations (CFR) Part 439.

EPA had first promulgated regulations for the pharmaceutical manufacturing point source category in 1976 (41 Federal Register (FR) 50676) for the following five subcategories of the industry:

- Subpart A - Fermentation Products Subcategory
- Subpart B - Extraction Products Subcategory
- Subpart C - Chemical Synthesis Subcategory
- Subpart D - Mixing, Compounding, and Formulating Subcategory
- Subpart E - Research Subcategory

The 1976 regulations established monthly best practicable control technology currently available (BPT) limitations for biochemical oxygen demand (BOD_5) and chemical oxygen demand (COD) for all subcategories. EPA did not establish daily maximum effluent limitations for these parameters. EPA established a pH limitation within the range of 6.0 to 9.0 standard units. The regulations also set maximum 30 day average concentration-based limitations for total suspended solids (TSS) for subparts B, D and E. EPA established no TSS limitations for subparts A and C.

On October 27, 1983, at 48 FR 49808, EPA revised the subcategory names to those used currently and promulgated revised BPT limitations as well as best available technology economically achievable (BAT) limitations and pretreatment standards for new sources (PSNS) and pretreatment standards for existing sources (PSES) for subparts A thru D to cover the toxic pollutant cyanide, conventional pollutants, BOD_5, TSS and pH and the nonconventional pollutant COD. The 1983 regulations retained the regulations for BOD_5 and COD established in 1976 but added concentration-based limitations for these parameters applicable to subparts B, D and E. EPA also promulgated BPT, BAT, PSES and PSNS for pH (6.0-9.0) and BAT concentration-based limitations controlling the discharge of cyanide for subpart A through D. While the Agency also had proposed new source performance standards (NSPS) for BOD_5, TSS and pH in the October 1983 notice, it did not adopt NSPS for these parameters. On December 16, 1986, at 51 FR 45094, EPA promulgated best conventional pollutant control technology (BCT) effluent limitations guidelines for BOD_5, TSS and pH for subparts A thru D. That final rule set BCT effluent limitations equal to the existing BPT effluent limitations guidelines for BOD_5, TSS, and pH.

The 1998 regulations amended the effluent limitations guidelines for subparts A through D. Facilities or operations involved in research continue to be subject to the regulations in subpart E.

Direct discharging facilities with operations in the four manufacturing subcategories were required to comply with the 1998 regulations by November 20, 1998. The compliance date for existing source indirect discharging facilities was as soon as possible, but no later than September 21, 2001. Permit writers and control authorities are required to issue permits (or other control mechanisms) to ensure that affected facilities are complying with the new regulations. **This document is specifically written to provide guidance to permitting and pretreatment control authorities in issuing National Pollutant Discharge Elimination System (NPDES) permits and permits (or other control mechanisms) to pharmaceutical facilities with manufacturing operations in the four subcategories discussed above.**
Permitting or pretreatment control authorities will need to determine which facilities fall under 40 CFR Part 439 and how to write the permits or pretreatment agreements for these facilities to ensure their

compliance under the new regulations. EPA has provided information in Sections 2 - 10 to help permit writers and pretreatment control authorities in this process.

- **Section 2** presents a brief overview of the NPDES Program and the National Pretreatment Program;
- **Section 3** presents the scope of the promulgated final effluent limitations guidelines and standards and describes which facilities are subject to the rule;
- **Section 4** discusses the pollutants regulated under 40 CFR Part 439 for facilities with operations in subparts A, B, C, D and E;
- **Section 5** discusses the technology bases for the effluent limitations guidelines and standards promulgated for facilities with operations in subparts A, B, C, D, and E;
- **Section 6** discusses the in-process and end-of-pipe points where affected facilities must demonstrate compliance with the rule;
- **Section 7** presents the effluent limitations guidelines and standards promulgated for facilities with operations in subparts A, B, C, D, and E;
- **Section 8** walks through the process of establishing permit limits for facilities with operations in subparts A, B, C, D, and E;
- **Section 9** presents five case studies as examples for establishing permits for facilities with operations in subparts A, B, C, D, and E; and
- **Section 10** contains a list of resources for additional guidance in establishing permits for affected facilities.

EPA's objective here is to provide guidance on issuing permits and pretreatment control mechanisms to facilities with operations in the above subcategories in an easy-to-read format. While this manual attempts to address many permitting issues and situations that may be covered by the regulation, there are other sources that may be helpful in developing permits/pretreatment control mechanism for facilities with operations in subparts A, B, C, D, and E. The manual identifies and references other sources throughout the text that can be accessed to get additional guidance. Also included in Section 10 is a list of these and other sources and how to order them, as well as a list of EPA and other authorities to contact for more guidance.

2. Overview of NPDES Program and National Pretreatment Program

This section presents a brief overview of the NPDES Permit program and the National Pretreatment Program. For more background information regarding EPA's programs to develop national standards for point source categories, refer to the *U.S. EPA NPDES Permit Writer's Manual* (EPA-833-B-96-003). In addition, a permit writer should also consult the *Industrial User Permitting Guidance Manual* (EPA-833/R-89-001).

2.1 What is the NPDES Permit Program?

Section 301(a) of the CWA prohibits the discharge of pollutants except in compliance with CWA Section 402, among other sections. Section 402 authorizes the issuance of NPDES permits for direct dischargers (i.e., existing or new industrial facilities that discharge process wastewaters from any point source into receiving waters). Permit writers must develop NPDES permits to control these discharges, using effluent limitations guidelines and standards and water-quality based effluent limitations.

2.1.1 What Are Effluent Limitations Guidelines and Standards?

EPA establishes effluent limitations guidelines and standards to require a minimum level of treatment for industrial point sources. EPA bases its effluent limitations guidelines and standards on the demonstrated performance of model process and treatment technologies that are found to be economically achievable by an industrial category or subcategory. Although effluent limitations guidelines and standards are based on the performance of model process and treatment technologies, EPA does not mandate the use of specific technologies. Dischargers are free to use any available control technique to meet the limitations.

2.1.2 What Are Water-Quality-Based Effluent Limitations?

All receiving waters have ambient water quality standards that are established by the states or EPA to maintain and protect designated uses of the receiving water (e.g., aquatic life-warm water habitat, public water supply, primary contact recreation). Permit writers may find that the application of the effluent limitations guidelines result in pollutant discharges that exceed the water quality standards in particular receiving waters. In such cases, permit writers are required by the CWA and federal guidelines to develop more stringent water-quality-based effluent limitations (WQBELs) for the pollutant to ensure that the water quality standards are met. States can use the total maximum daily load (TMDL) process as one way of quantifying the allowable pollutant loadings in receiving waters, based on the relationship between pollution sources and in-stream water quality standards.

Because EPA and state permitting authorities are familiar with their respective water quality standards and knowledgeable in waste load allocations and other procedures to maintain water quality standards these issues are not addressed in this document. To learn more about how TMDLs are developed, refer to *Guidance for Water-Quality-Based Decisions: The TMDL Process* (EPA 440/4-91-001). To learn how to apply water quality standards in NPDES permits, refer to the *Technical Support Document for Water Quality-Based Toxics Control* (EPA/505/2-90-001).

2.2 What Is the National Pretreatment Program?

The CWA requires EPA to promulgate nationally applicable pretreatment standards that restrict pollutant discharges from facilities that discharge wastewater indirectly through sewers flowing to publicly-owned treatment works (POTWs). (See Section 307(b) and (c), 33 U.S.C. 1317(b) & (c)). National pretreatment standards are established for those pollutants in wastewater from indirect dischargers that may pass

through, interfere with, or are otherwise incompatible with POTW operations. Generally, pretreatment standards are designed to ensure that wastewaters from direct and indirect industrial dischargers are subject to similar levels of treatment. In addition, all POTWs that must develop local pretreatment programs are required to implement specific local treatment limits applicable to their industrial indirect dischargers to prevent pass through and interference and to prevent the introduction into POTWs of certain pollutants (e.g., pollutants that create a fire or explosion hazard, corrosion or pollutants that result in toxic gases that may cause acute worker health or safety problems). All other POTWs must establish local limits to prevent pass through or interference to ensure compliance with the POTW's NPDES permit or sewage sludge uses. (See 40 CFR 403.5). CWA Section 402(b)(8) requires that permits for certain POTWs receiving pollutants from significant industrial sources subject to pretreatment standards under CWA Section 307(b) must establish a pretreatment program to ensure compliance with these standards. EPA has published regulations to define the requirements of this POTW pretreatment control program.

2.2.1 What Are National Pretreatment Standards?

40 CFR Part 403 presents the general pretreatment regulations for existing and new sources of pollution. The following table presents the content of each section of 40 CFR Part 403.

Table 2-1: Contents of 40 CFR Part 403

40 CFR Section	Content
403.1	Purpose and applicability
403.2	Objective of general pretreatment regulations
403.3	Definitions
403.4	State or local law
403.5	National pretreatment standards: prohibited discharges
403.6	National pretreatment standards: categorical standards
403.7	Removal credits
403.8	Pretreatment program requirements: development and implementation by POTW
403.9	POTW pretreatment programs and/or authorization to revise pretreatment standards: submission for approval
403.10	Development and submission of NPDES state pretreatment programs
403.11	Approval procedures for POTW pretreatment programs and POTW granting of removal credits.
403.12	Reporting requirements for POTWs and industrial users
403.13	Variances from categorical pretreatment standards for fundamentally different factors
403.14	Confidentiality
403.15	Net/gross calculation
403.16	Upset provision
403.17	Bypass
403.18	Modification of POTW pretreatment programs

40 CFR 403.5(a)(1) generally prohibits users of a POTW (indirect dischargers) from discharging pollutants to the POTW that cause pass-through or interference. Pass-through is defined as a discharge that exits the POTW into waters of the United States in quantities or concentrations that, alone or in conjunction with a discharge or discharges from other sources, causes a violation of any requirement of the POTW's NPDES permit. Interference is defined as a discharge that, alone or in conjunction with a discharge or discharges from other sources, both: (1) inhibits or disrupts the POTW, its treatment processes, or its operations; or its sludge processes, use, or disposal; and (2) causes the POTW to violate any requirement of its NPDES permit, or prevents sewage sludge use or disposal (40 CFR 403.3).

40 CFR 403.5(c) and 40 CFR 403.8 specify that POTWs that have flows greater than 5.0 million gallons per day (mgd) and that receive pollutants that pass through or interfere with their operations or are otherwise subject to categorical pretreatment standards must develop and enforce local limits to comply with the National Pretreatment Standards.

2.3 Applicability of Effluent Limitations Guidelines and Standards

Pharmaceutical facilities that discharge waters to receiving streams or POTWs are required to meet one (or more) of the following effluent limitations guidelines and standards established by the CWA.

Table 2-2: Description of Effluent Limitations Guidelines and Standards

Acronym	Guideline or Standard	Applicable pollutants and discharge type [a]
BPT	Best practicable control technology currently available	Conventional pollutants at an existing direct discharger [b]
BCT	Best conventional pollutant control technology	Conventional pollutants at an existing direct discharger
BAT	Best available technology economically achievable	Toxic and nonconventional pollutants at an existing direct discharger
NSPS	New source performance standards	Conventional, toxic, and nonconventional pollutants at a new source, direct discharger
PSES	Pretreatment standards for existing sources	Toxic and nonconventional pollutants at an existing indirect discharger
PSNS	Pretreatment standards for new sources	Toxic and nonconventional pollutants at a new source, indirect discharger

[a] These terms are defined in the glossary.
[b] Nonconventional and priority pollutants can also be controlled by BPT regulations.

With the September 21, 1998 promulgation of the regulation, EPA has revised BPT, BAT, NSPS, PSES, and PSNS for the pharmaceutical manufacturing point source category. **Note that although this document focuses on these new effluent limitations guidelines and standards, those limitations and standards that were not revised remain in effect unless otherwise stated in the September 21, 1998 promulgated rule.** Table 2-3 summarizes the applicability of these effluent limitations guidelines and standards.

Table 2-3: Effluent Limitations Guidelines and Standards Applicable to Each Program

Program	Type of Discharger	Existing or New Source?	Applicable Guidelines and Standards Previously Established	Additional Guidelines and Standards (from 9/21/98 Rule)
NPDES Permit Program	Direct Discharger	Existing Source	BCT BPT BAT	 BPT BAT
		New Source	NSPS	NSPS
National Pretreatment Program	Indirect Discharger	Existing Source	PSES	PSES
		New Source	PSNS	PSNS

3. Scope of 40 CFR Part 439

The revisions to the effluent limitations guidelines and standards promulgated on September 21, 1998 apply only to subparts A through D of the pharmaceutical manufacturing industry. Subpart E (Research) was not revised by the September 21, 1998 final regulations. Subpart E operations at stand-alone facilities or at manufacturing facilities with subpart A, B, C, and/or D operations continue to be subject to the existing BPT effluent limitations guidelines for subpart E, revised October 27, 1983 (40 CFR 439.52).

Pharmaceutical manufacturers use many different raw materials and manufacturing processes to create a wide range of products with therapeutic value. Pharmaceutical products are produced by a number of processes. These include the following: chemical synthesis, fermentation, extraction from naturally occurring plant or animal substances, mixing, compounding, and formulating operations, or by refining a technical grade product.

The regulations establish different requirements depending on whether a manufacturing operation is an existing source or a new source. The pharmaceutical manufacturing industry regularly may make equipment and process changes to existing manufacturing processes. Consequently, permitting authorities should carefully review EPA regulations before deciding whether a particular source of discharge is an *existing source* or a *new source*.

The definition of new source for direct dischargers is at 40 CFR 122.2 and the new source definition for indirect dischargers is at 40 CFR 403.3. Direct discharging pharmaceutical new sources have to meet more stringent BOD_5 and TSS standards than existing sources. In the case of indirect facilities, PSES and PSNS are identical.

The pharmaceutical guidelines and standards regulation applies generally, but not exclusively, to process wastewater discharges resulting from the manufacture of pharmaceutical products and from pharmaceutical research reported within three specified U.S. Department of Commerce Bureau of the Census Standard Industrial Classification system (SIC) groups and to the manufacture of certain pharmaceutical products not reported under the three SIC codes. The regulation does not apply to dischargers from the manufacture of pharmaceutical products included in eight other SIC subgroups and three other identified pharmaceutical products. Which pharmaceutical product process wastewaters are, and are not, subject to this regulation is explained in further detail at 40 CFR 439.0. The currently applicable regulations may be found in any edition of the CFR dated July, 1999 or later.

A logic chart presenting the applicability of the September 21, 1998 pharmaceutical effluent limitations guidelines and standards is presented in Figure 3-1.

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

- Products covered by the U.S. Department of Commerce, Bureau of the Census Standard Industrial Classification (SIC) Code No. 2836, with the exception of diagnostic substances. (Products covered by SIC Code No. 2836 were formerly covered under the 1977 SIC Code No. 2831.)

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

- Pharmaceutical products covered by SIC Code No. 2834.

- All fermentation, natural extraction, chemical synthesis and formulation products considered to be pharmaceutically active ingredients by the Food and Drug Administration (21 CFR 210.3(b)(7)) that are not covered by SIC Code Nos. 2833, 2834, or 2836.

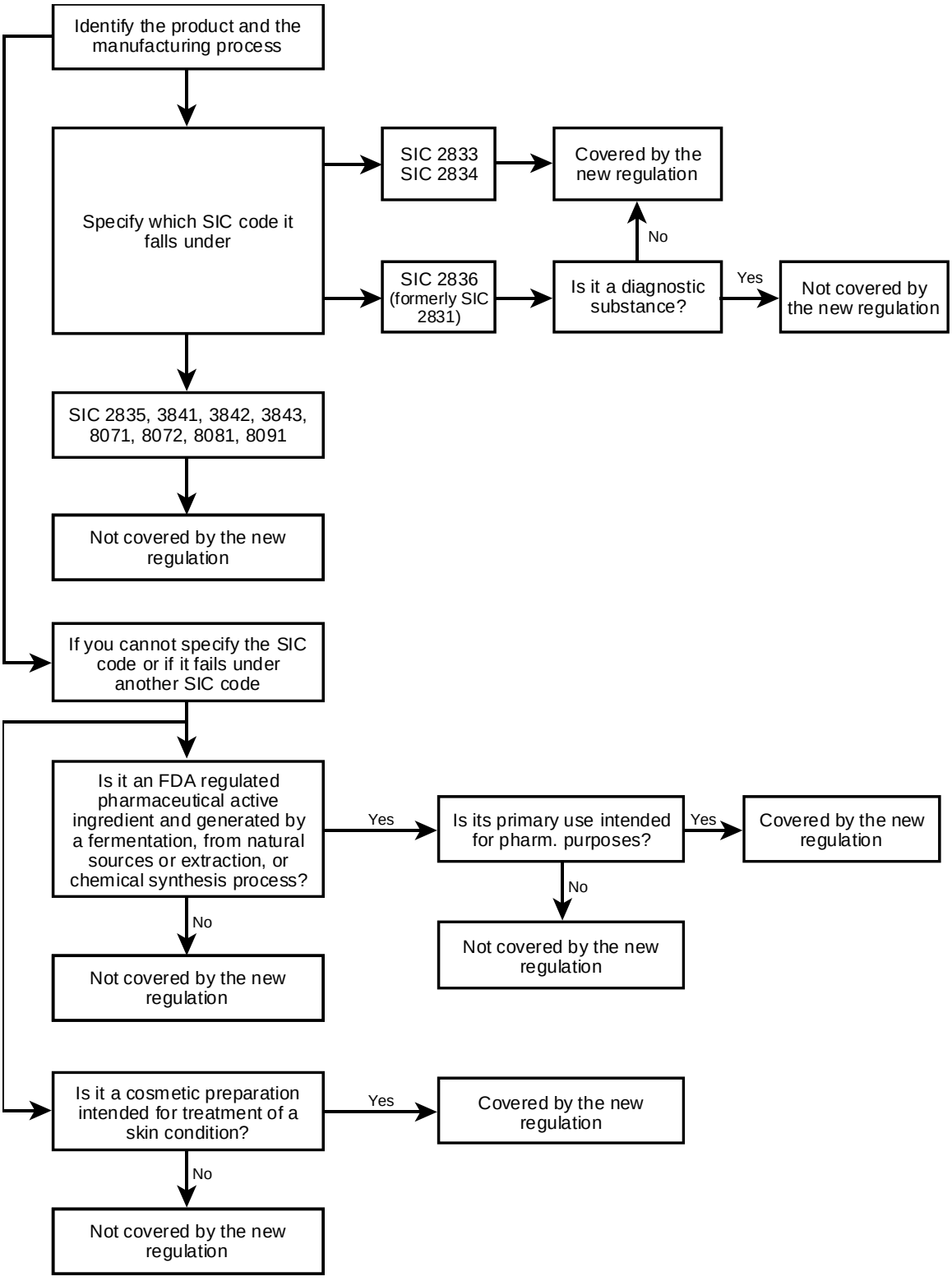


Figure 3-1: Product Applicability Basis of the September 21, 1998 Pharmaceutical Manufacturing Effluent Limitations Guidelines

- Multiple end-use products derived from pharmaceutical manufacturing operations (e.g., components of formulations, intermediates, or final products, provided that the primary use of the product is intended for pharmaceutical purposes).

- Products not covered by SIC Code Nos. 2833, 2834, and 2836 or other categorical limitations and standards if they are manufactured by a pharmaceutical manufacturer by processes that generate wastewaters that in turn closely correspond to those of pharmaceutical products. (An example of such a product is citric acid.)

- Cosmetic preparations covered by SIC Code No. 2844 that contain pharmaceutically active ingredients or ingredients intended for treatment of some skin condition. (This group of preparations does not include products such as lipsticks or perfumes that serve to enhance appearance or to provide a pleasing odor, but do not provide skin care. In general, this also excludes deodorants, manicure preparations, shaving preparations and non-medicated shampoos that do not function primarily as a skin treatment.)

Products or activities specifically excluded from the pharmaceutical manufacturing category are:

- Surgical and medical instruments and apparatus reported under SIC Code No. 3841.

- Orthopedic, prosthetic, and surgical appliances and supplies reported under SIC Code No. 3842.

- Dental equipment and supplies reported under SIC Code No. 3843.

- Medical laboratories services reported under SIC Code No. 8071.

- Dental laboratories services reported under SIC Code No. 8072.

- Outpatient care facility services reported under SIC Code No. 8081.

- Health and allied services reported under SIC Code No. 8091, and not classified elsewhere.

- Diagnostic devices other than those reported under SIC Code No. 3841.

- Animal feeds that include pharmaceutical active ingredients such as vitamins and antibiotics, where the major portion of the product is non-pharmaceutical, and the resulting process wastewater is not characteristic of process wastewater from the manufacture of pharmaceutical products.

- Foods and beverage products fortified with vitamins or other pharmaceutical active ingredients, where the major portion of the product is non-pharmaceutical, and the resulting process wastewater is not characteristic of process wastewater from the manufacture of pharmaceutical products.

Since the final pharmaceutical manufacturing regulations were promulgated on Sept. 21, 1998, many pharmaceutical and other manufacturers have begun producing bioengineered products using bioengineering techniques developed from bench scale research operations. While these operations are generally similar to those of Part 439, the provisions of these subparts do not apply to these bioengineering operations. Thus, permit writers should develop applicable limitations and standards for these operations based on best professional judgment. The limitations and standards in Part 439 may be a useful resource to the permit writer in determining appropriate limitations and standards when the character of the wastewater from the bioengineering operations is similar to that of the Part 439 wastewater from like operations.

QA/QC laboratory wastewaters which do not come in contact with pharmaceutical manufacturing operations and are discharged separately (i.e., are not commingled with other regulated waste streams upstream of the compliance monitoring point) are excluded from the subpart A, B, C, and D limitations.

In addition, facilities regulated by the organic chemicals, plastics and synthetic fibers (OCPSF) effluent limitations guidelines and standards (40 CFR Part 414) that manufacture pharmaceutical products and intermediates will be subject to the OCPSF effluent limitations guidelines and standards provided that the wastewater generated as a result of the manufacture of pharmaceutical products and intermediates is less than 50% of the total process wastewater flow at the facility.

Example 1: A facility manufactures medicated shampoo that treats dandruff and is classified in SIC Code 2844. Is this facility covered under the pharmaceutical September 21, 1998 regulation?

This facility would be subject to the pharmaceutical regulation since it manufactures products which contain a pharmaceutically active ingredient generated by a fermentation, natural source (plant and animal), extraction, chemical synthesis, or formulation process.

Example 2: A facility manufactures herbal medicines that do not contain an FDA regulated pharmaceutically active ingredient (as defined in 21 CFR 210.3(b)(7)). Is this facility subject to the pharmaceutical September 21, 1998 regulation?

This facility would not be subject to the pharmaceutical regulation since it does not manufacture or process a pharmaceutically active ingredient.

4. What are the Pollutants Regulated by the Rule

The tables below show what pollutants are regulated under the pharmaceutical regulations.

Permit writers and others should recall that different standards will apply to sources that are new depending on when the sources was a new source. EPA amended paragraph (c) in four sections of the regulation (439.15(c), 439.25(c), 439.35(c), and 439.45(c)) to state clearly that any new source that commenced discharging after November 21, 1988 and before November 20, 1998 must continue to achieve the standards specified for 40 CFR Part 439 in the October 27, 1983 *Federal Register* (48 FR 49808). These standards applied until the applicable time period specified in 40 CFR 122.29(d)(1) (10 years) had expired. After this, the facility must meet the current BCT and BAT requirements.

Table 4-1: Pollutants Regulated Under BPT

Pollutants	Subpart A	Subpart B	Subpart C	Subpart D	Subpart E
BOD_5	✓	✓ *	✓	✓*	✓
COD	✓	✓	✓	✓	✓
TSS	✓	✓	✓	✓	✓
pH	✓	✓	✓	✓	✓
Cyanide	✓		✓		

Table 4-2: Pollutants Regulated Under BCT

Pollutants	Subpart A	Subpart B	Subpart C	Subpart D	Subpart E
BOD_5	✓	✓	✓	✓	
TSS	✓	✓	✓	✓	
pH	✓	✓	✓	✓	

*On March 13, 2003, EPA corrected the omission of a minimum BOD_5 limitation from two sections of the regulation promulgated on September 21, 1998 by adding to §§ 439.22(a) and 439.42(a) the phrase "except that no facility shall be required to attain a monthly average limitation for BOD_5 that is less than the equivalent of 45 mg/L."

Table 4-3: Pollutants Regulated Under BAT

Pollutants	Subpart A	Subpart B	Subpart C	Subpart D	Subpart E
COD	✓	✓	✓	✓	
Acetone	✓		✓		
Acetonitrile	✓		✓		
Ammonia	✓		✓		
n-Amyl acetate	✓		✓		
Amyl alcohol	✓		✓		
Benzene	✓		✓		
n-Butyl alcohol	✓		✓		
Chlorobenzene	✓		✓		
Chloroform	✓		✓		
Cyanide	✓ [a]	[a]	✓ [a]	[a]	
o-Dichlorobenzene	✓		✓		
1,2-Dichloroethane	✓		✓		
Diethylamine	✓		✓		
Dimethyl sulfoxide	✓		✓		
Ethanol	✓		✓		
Ethyl acetate	✓		✓		
n-Heptane	✓		✓		
n-Hexane	✓		✓		
Isobutyraldehyde	✓		✓		
Isopropanol	✓		✓		
Isopropyl acetate	✓		✓		
Isopropyl ether	✓		✓		
Methanol	✓		✓		
Methyl cellosolve	✓		✓		
Methyl formate	✓		✓		
Methyl isobutyl ketone (MIBK)	✓		✓		
Methylene chloride	✓		✓		
Phenol	✓		✓		
Tetrahydrofuran	✓		✓		
Toluene	✓		✓		
Triethylamine	✓		✓		
Xylenes	✓		✓		

[a] These pollutants were regulated by the previous regulations.

Table 4-4: Pollutants Regulated Under NSPS

Pollutants	Subpart A	Subpart B	Subpart C	Subpart D	Subpart E
BOD_5	✓	✓	✓	✓	
COD	✓	✓	✓	✓	
pH	✓ [(a)]	✓ [(a)]	✓ [(a)]	✓ [(a)]	
TSS	✓	✓	✓	✓	
Acetone	✓		✓		
Acetonitrile	✓		✓		
Ammonia	✓		✓		
n-Amyl acetate	✓		✓		
Amyl alcohol	✓		✓		
Benzene	✓		✓		
n-Butyl acetate	✓		✓		
Chlorobenzene	✓		✓		
Chloroform	✓		✓		
Cyanide	✓ [(a)]	[(a)]	✓ [(a)]	[(a)]	
o-Dichlorobenzene	✓		✓		
1,2-Dichloroethane	✓		✓		
Diethylamine	✓		✓		
Dimethyl sulfoxide	✓		✓		
Ethanol	✓		✓		
Ethyl acetate	✓		✓		
n-Heptane	✓		✓		
n-Hexane	✓		✓		
Isobutyraldehyde	✓		✓		
Isopropanol	✓		✓		
Isopropyl acetate	✓		✓		
Isopropyl ether	✓		✓		
Methanol	✓		✓		
Methyl cellosolve	✓		✓		
Methyl formate	✓		✓		
Methyl isobutyl ketone (MIBK)	✓		✓		
Methylene chloride	✓		✓		
Phenol	✓		✓		
Tetrahydrofuran	✓		✓		
Toluene	✓		✓		
Triethylamine	✓		✓		
Xylenes	✓		✓		

[(a)] These pollutants were regulated by the previous regulations.

Table 4-5: Pollutants Regulated Under PSES and PSNS

Pollutants	Subpart A	Subpart B	Subpart C	Subpart D	Subpart E
Acetone	✓	✓	✓	✓	
Ammonia	✓		✓		
n-Amyl acetate	✓	✓	✓	✓	
Benzene	✓		✓		
n-Butyl acetate	✓		✓		
Chlorobenzene	✓		✓		
Chloroform	✓		✓		
Cyanide	✓ [a]	[a]	✓ [a]	[a]	
o-Dichlorobenzene	✓		✓		
1,2-Dichloroethane	✓		✓		
Diethylamine	✓		✓		
Ethyl acetate	✓	✓	✓	✓	
n-Heptane	✓		✓		
n-Hexane	✓		✓		
Isobutyraldehyde	✓		✓		
Isopropyl acetate	✓	✓	✓	✓	
Isopropyl ether	✓		✓		
Methyl formate	✓		✓		
Methyl isobutyl ketone (MIBK)	✓		✓		
Methylene chloride	✓	✓	✓	✓	
Tetrahydrofuran	✓		✓		
Toluene	✓		✓		
Triethylamine	✓		✓		
Xylenes	✓		✓		

[a] These pollutants were regulated by the previous regulations.

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

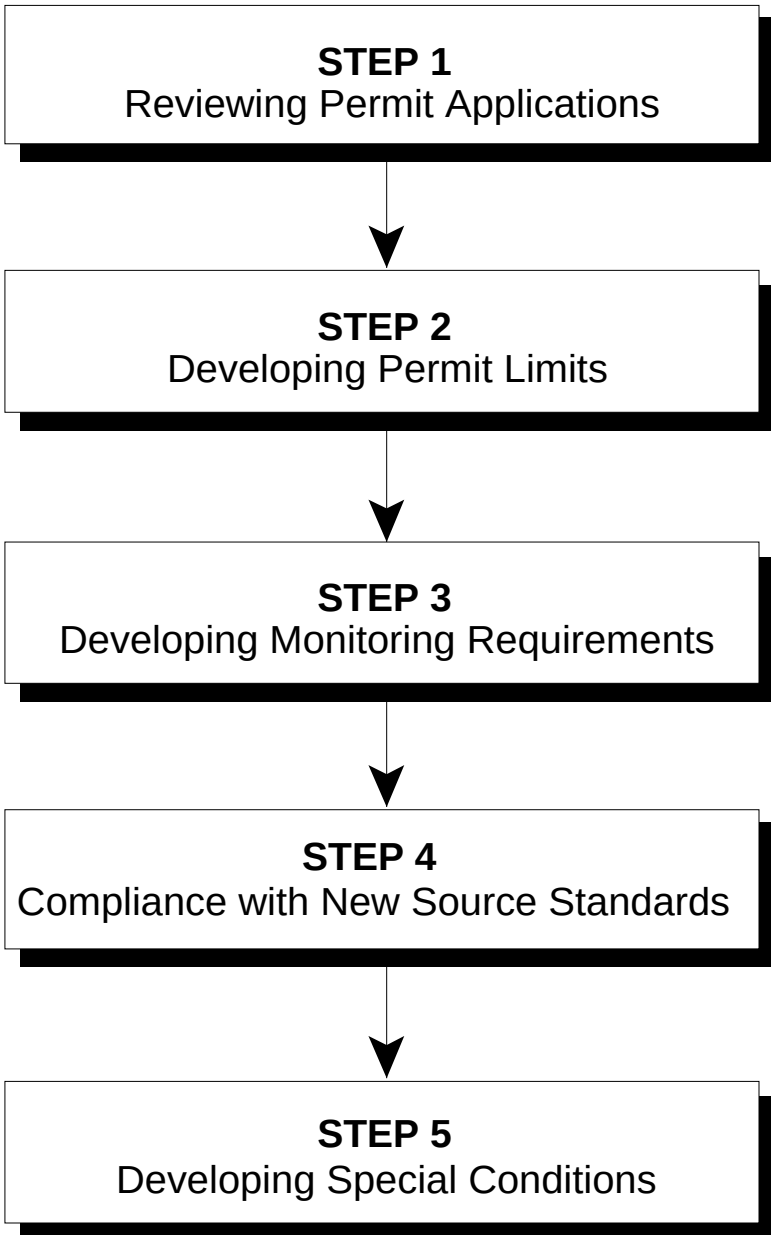
[(a)] Cyanide effluent limit established in the 1983 final rule.
[(b)] Ammonia is only regulated for indirect dischargers that discharge to non-nitrifying POTWs.

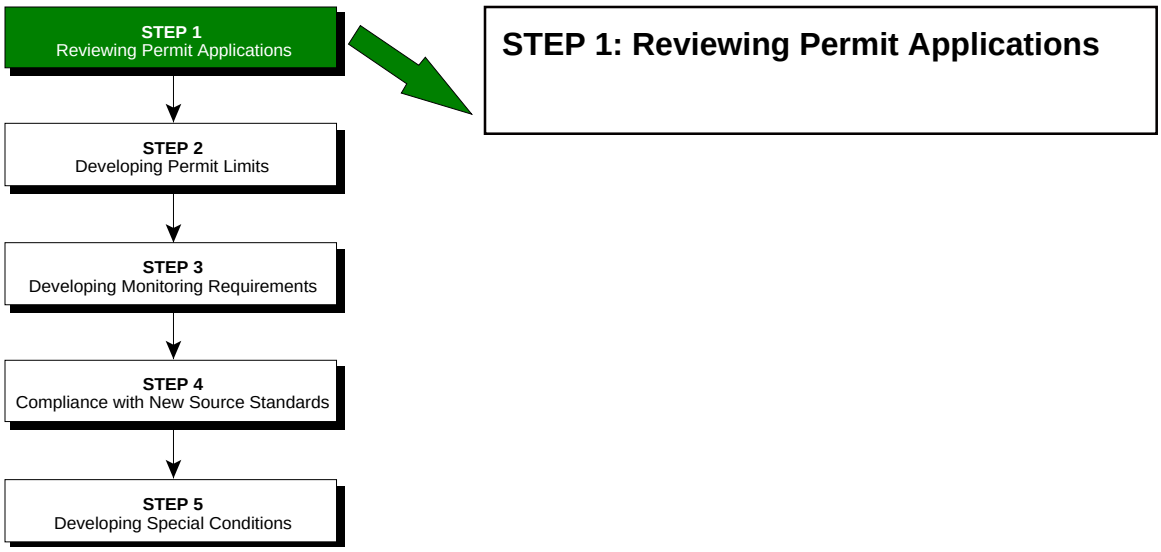
Table 7-7: PSES and PSNS for Subpart B and D Operations

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

8. How Are Permits Developed for Facilities with Operations in Subparts A, B, C, D, and E?

This section discusses the step-by-step process of establishing permit limits using effluent limitations guidelines and standards for facilities with operations in subparts A, B, C, D, and E. The discussion covers the following steps to aid permit writers and control authorities in establishing permits:





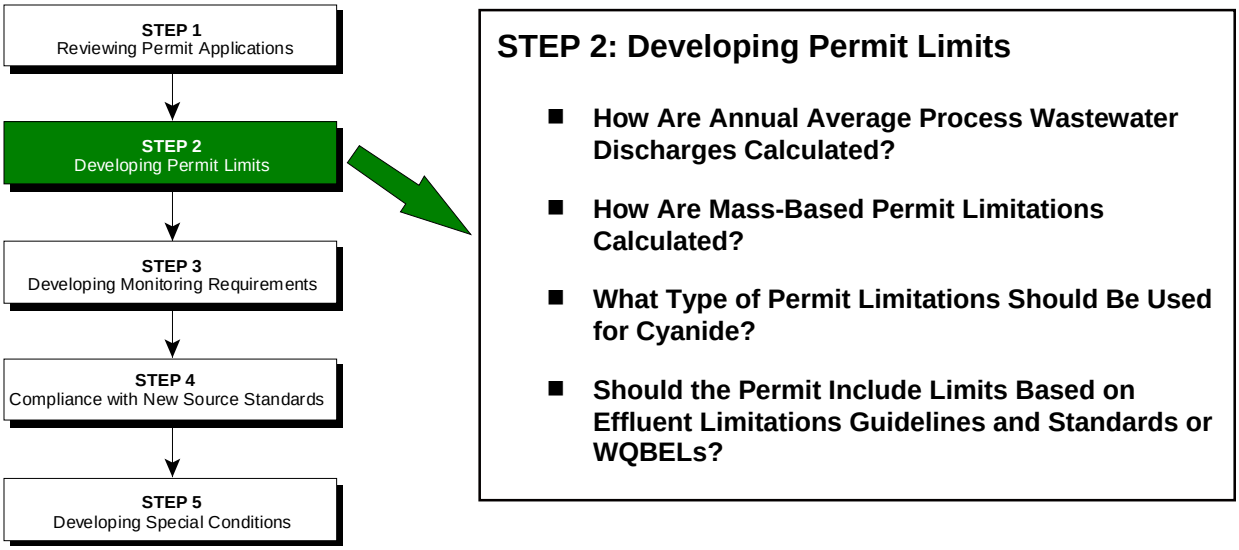
8.1 Reviewing Permit Applications

All facilities that discharge process wastewaters into receiving streams must submit the following forms, or the state control authority's applicable forms, where the state has an authorized NPDES permit program, when applying for an NPDES permit:

1. Form 1, which includes basic facility information and the SIC codes for the products manufactured; and

2. Form 2C (existing sources) or Form 2D (new sources), which includes outfall information, flow information or projections, and production information or projections.

Additional supporting information, associated with the facility's receiving stream, may include Total Maximum Daily Loads (TMDLs), Whole Effluent Toxicity (WET) test data, existing waste load allocations, and in-stream data and studies. These forms and supporting material provide the information necessary for establishing NPDES permits for facilities.



8.2 Developing Permit Limits

As part of the permit process, permit writers must apply the effluent limitations guidelines and standards developed by EPA to establish numerical permit limits for facilities. Note that permits may also include WQBELs (see section 2). This document; however, focuses on the development of permit limits based on effluent limitations guidelines and standards for the pharmaceutical point source category.

As discussed in the body of the *Development Document for Effluent Limitations Guidelines and Standards for the Pharmaceutical Manufacturing Point Source Category* (EPA 821-R-98-005), the pharmaceutical manufacturing industry effluent limitations guidelines and standards are concentration based and adhere to the "building block" concept, where applicable. Where applicable, each regulated wastestream in an outfall is assigned a mass-based discharge allowance based on a calculation of its applicable concentration-based limitation and appropriate process flow. The sum of the allowances is the total mass discharge allowance for the outfall.

Mass limitations for unregulated process wastewater streams and dilution streams at direct discharging facilities are established by the NPDES permit authority using best professional judgment (BPJ). Where process effluent is mixed prior to treatment with wastewaters other than those generated by the regular process (e.g., unregulated process wastewater streams and dilution streams) at indirect discharging facilities, the Control Authority may develop alternate limitations (see 40 CFR 403.12(a) and 40 CFR 403.3) by using the combined waste stream formula (see 40 CFR 403.6(e)(i),(ii)).

Permit writers may elect to develop limitations or standards for excluded wastes which are not regulated on a national level, in a facility permit under certain conditions. In the case of an indirect discharge, the pretreatment authority must develop local limits for excluded wastes under certain conditions (pass through or interference or as necessary to prevent violations of the POTW's NPDES permit). For the specific circumstances, see 40 CFR 403.5. A pretreatment authority may also develop limits for excluded wastes where otherwise authorized or required under state law. The permit writer or pretreatment authority decides if a facility may or may not discharge an excluded waste and sets the conditions whereby a facility may or may not discharge this waste. Excluded wastes include off-specification fermentation batches, trimethyl silanol, and active antimicrobial materials.

8.2.1 How Are Annual Average Process Wastewater Discharges Calculated?

In implementing the final BPT, BAT, and NSPS limitations and standards, permit writers need to account for the facility's nonprocess wastewater contained in the effluent being discharged in developing either mass or concentration based permit limits. EPA developed the final effluent limitations guidelines and standards from data gathered at plants which had less than 25 percent nonprocess wastewater in the total plant discharge that is subject to the regulations. Therefore, when permit writers develop end-of-pipe effluent limitations, they should use a reasonable estimate of process wastewater discharge flow, allowing for up to 25 percent nonprocess water through treatment. The flow estimates and the concentration-based limitations are used to develop mass-based limitations for the NPDES permit.

"Process wastewater discharge" is defined, in general, by 40 CFR 122.2. In the case of pharmaceutical manufacturing operations, wastewater resulting from the manufacture of pharmaceutical products include those wastewaters that come in direct contact with raw materials, intermediate products, and final products, and surface runoff from the immediate process area that has the potential to become contaminated. Noncontact cooling waters, utility wastewaters, general site surface runoff, groundwater, and other nonprocess water generated on site are specifically excluded from this definition. The appropriate process wastewater discharge flow for each stream to be used when developing mass-based limitations must be determined by permit writers on a case-by-case basis using current information provided by the facility seeking the permit. Both the NPDES permit regulations and the general pretreatment regulations prohibit the use of dilution flows in determining mass limitations in cases where permit writers deem the process wastewater discharge flow claimed by the permittee are excessive and represent dilution flows. Permit writers may develop a more appropriate process wastewater discharge flow for use in computing the mass-based permit limitations. Permit writers should review the following items to evaluate whether process wastewater discharge flow reflects the addition of dilution flows:

- The component flows to ensure that the claimed flows are, in fact, process wastewater discharge flows as defined by 40 CFR 122.2.

- The plant operations to ensure that sound water conservation practices are being followed. Examples include minimization of process water uses and reuse or recycle of intermediate process waters or treated wastewaters at the process area and in wastewater treatment operations (pump seals, equipment and area washdowns, etc.)

- Barometric condenser use at the process level. Often, barometric condensers will generate relatively large volumes of slightly contaminated water. Replacing barometric condensers with surface condensers can reduce wastewater volumes significantly and result in collection of condensates that may be returned to the process.

To establish a NPDES permit for a direct discharging facility, permit writers should determine which subcategories the facility's operations fall within and use the corresponding concentration-based effluent limitations as a basis for developing the mass-based limitations. Permit writers should evaluate the facility's long-term average process and nonprocess wastewater discharge flow. The flow volume representing 25% or less of the total flow should be included in the volume used to calculate allowable mass discharges. Any additional volume would have to be evaluated on a case-by-case basis to determine what, if any, mass allowances are appropriate. The permit writer should consider only the sources of "process wastewater discharge," as defined previously, and only sources of nonprocess wastewater such that the percentage of nonprocess wastewaters in the total regulated flow is no more than 25%. The long-term average flow is defined as the average of daily flow measurements calculated over at least a year (usually at least three years of flow data are used to account for fluctuations). However, permit writers have flexibility when determining a facility's long-term average flow rate. If a facility is expecting significant changes in production as represented by previous year(s) data, permit writers may establish a flow rate expected to be representative during the permit term.

In the event that no historical data or actual process wastewater flow data exist (such as for a new source), permit writers should establish a reasonable estimate of the facility's projected flow. This may include a request for the facility to measure process wastewater flows for a representative period of time to establish a flow basis. Permit writers are advised to establish a flow rate that is expected to be representative during the entire term of the permit. If a plant is planning significant changes in production during the effective period of the permit, permit writers may consider establishing multiple tiers of limitations as a function of these changes. Alternatively, a permit may be modified during its term, either at the request of the permittee, permitter, or another party, or on EPA's initiative, to increase or decrease the flow basis in response to a significant change in production (40 CFR 124.5, 122.62). A change in production may be an "alteration" of the permitted activity or "new information" that would provide the basis for a permit modification (40 CFR 122.62(a)).

8.2.2 How Are Mass-Based Permit Limitations Calculated For Direct Dischargers?

For NPDES permits, after determining the facility's long-term average process wastewater flow, permit writers can use the long-term average daily flow rate or other established flow rate to convert concentration-based limitations into mass-based limitations. The following equation can be used by the permit writer to convert a concentration-based limitation into a mass-based limitation:

$$L_m = L_c \times F \times k_1$$

where:

- L_m = mass-based effluent limitation, lbs/day
- L_c = concentration-based limitation, mg/L
- F = long-term average process wastewater discharge, gal/day
- k_1 = unit conversion factor, (L × lbs)/(gal × mg).

For this example, the unit conversion factor, k_1 is used to convert from [(mg/L)×(gal/day)] to (lbs/day) as follows:

$$\mathbf{k} = \frac{1\ \text{L}}{0.264179\ \text{gal}} \times \frac{1\ \text{g}}{1{,}000\ \text{mg}} \times \frac{1\ \text{lb}}{453.592\ \text{g}} = 8.345 \times 10^{-6} \times \frac{\text{L lb}}{\text{gal mg}}$$

If the concentration based limitations are expressed as μg/L, the unit conversion factor k_2 can be used to convert from [(μg/L) × (gal/day)] to (lbs/day) as follows:

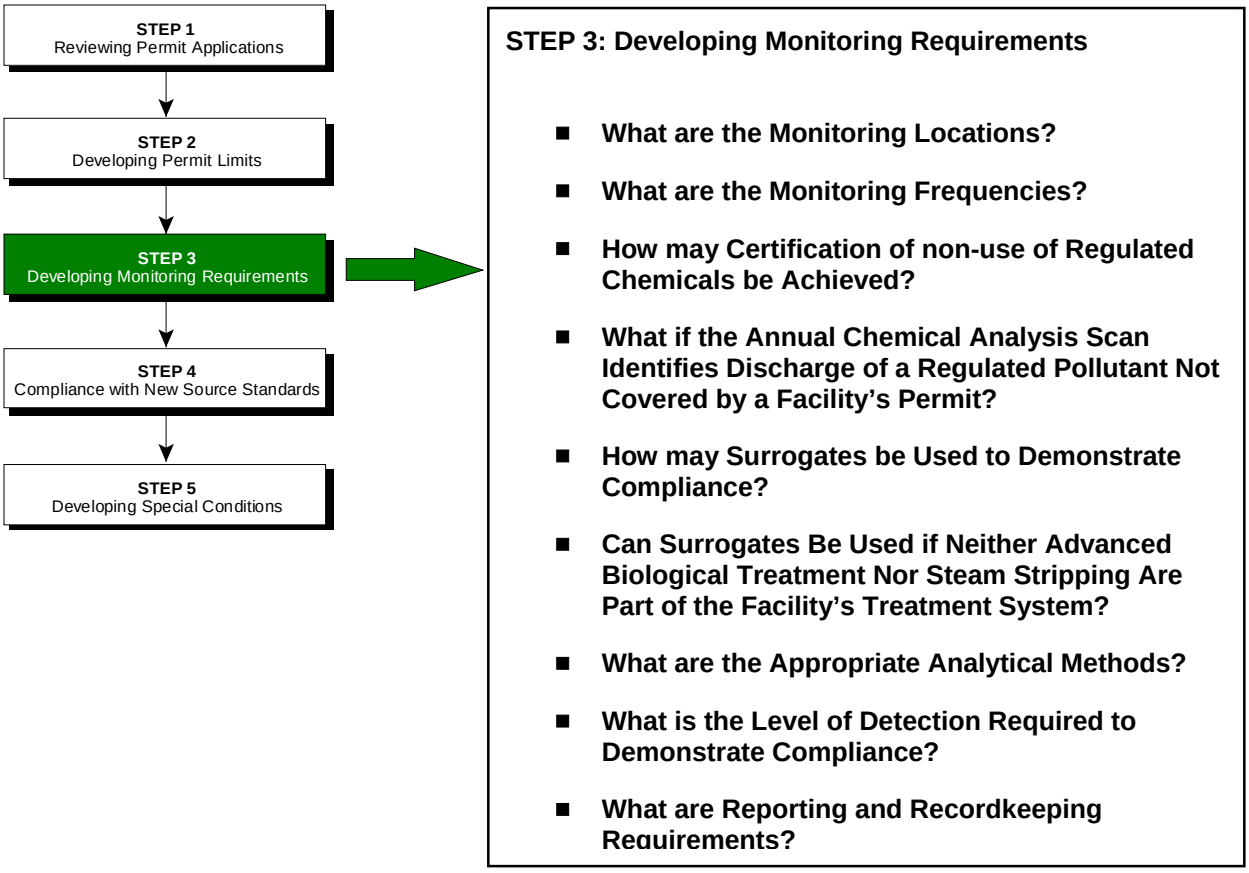
$$k_2 = \frac{1\ \text{L}}{0.264179\ \text{gal}} \times \frac{1\ \text{g}}{1{,}000{,}000\ \mu\text{g}} \times \frac{1\ \text{lb}}{453.592\ \text{g}} = 8.345 \times 10^{-9} \times \frac{\text{L lb}}{\text{gal}\ \mu\text{g}}$$

8.2.3 What Type of Permit Limitations Should Be Used for Cyanide?

EPA expects that permit limitations for cyanide, based on the 1983 PSES limitations, at in-plant locations will be concentration-based, and not converted to mass limits. A concentration basis should be used for cyanide because it offers a direct benchmark to assess whether the in-plant control technology is achieving the intended PSES and PSNS levels. In-plant wastestreams that require control may be generated or treated on a variable, batch basis. In such a setting, mass-based permit limitations are difficult to establish accurately, and compliance is hindered because the permitted facility cannot make a direct measurement to determine if its control technology is performing at the required level. Concentration-based permit limitations eliminate these problems and offer a direct measure of cyanide to both the permitting authority and the permitted facility that PSES and PSNS performance levels are being achieved.

8.2.4 Should the NPDES Permit Include Limits Based on Effluent Limitations Guidelines or WQBELs?

All receiving waters have water quality standards that are established by the states or EPA that protect the designated uses of the receiving water. After determining the allowable limits based on effluent limitations guidelines and standards, permit writers must compare them to the receiving water's WQBELs. If limits based on effluent limitations guidelines and standards for a particular pollutant result in discharges that exceed the WQBELs for the receiving water, permit writers must establish permit limits that are based on WQBELs (see Section 2 for more information regarding WQBELs).



8.3 Developing Monitoring Requirements

One of the permit writer's responsibilities is to establish monitoring requirements for facilities with operations in subparts A, B, C, D, and E. NPDES permits require dischargers to monitor their effluent to ensure that they are complying with permit limitations. As specified in 40 CFR 122.41, 122.44, and 122.48, all NPDES permits must specify requirements for using, maintaining, and installing (if appropriate) monitoring equipment; monitoring frequencies; analytical methods; and reporting and recordkeeping. Control authorities generally require similar monitoring techniques and frequencies at indirect discharging facilities. In addition to monitoring, etc., this section also focuses on the following unique aspects of the revised rule that relate to compliance monitoring:

- How may facilities certify non-use of a regulated chemical?
- How may surrogates be used to demonstrate compliance?
- What are the required analytical methods and the minimum levels of detection of each method?
- What other process parameters must be monitored to demonstrate that samples are representative?

8.3.1 What Are the Monitoring Locations?

Permit writers must require facilities to monitor their effluent in order to determine compliance with the effluent limitations guidelines and standards promulgated by EPA (see Section 6). The BPT, BAT, and NSPS effluent limitations for ammonia, BOD_5, TSS, pH, COD, and the organic pollutants are end-of-pipe limitations that are applicable to the process wastewater fraction of the final effluent at the point of discharge to waters of the United States. Compliance monitoring for cyanide at facilities with operations in subparts A or C 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 sufficient information exists to use the end-of-pipe monitoring results to determine compliance at the required in-plant location.

The PSES and PSNS for ammonia and the organic pollutants are applicable at an end-of-pipe discharge point prior to discharge to the POTW sewer system. Compliance monitoring for cyanide at facilities with operations in subparts A or C 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 sufficient information exists to use the end-of-pipe monitoring results to determine compliance at the required in-plant location. In some cases, where there are detection or compliance determination issues, in-plant monitoring for organics may be used.

8.3.2 What Are the Monitoring Frequencies and Sampling Protocols?

Permit writers must determine an appropriate frequency for compliance monitoring for ammonia, BOD_5, COD, TSS, pH, and other organic constituents. EPA's monitoring costs for this regulation assumed compliance monitoring for ammonia and all regulated organic constituents on a weekly basis, and monitoring for BOD_5, COD, TSS, and pH on a daily basis. However, the permit writer has the obligation to set a monitoring frequency in accordance with 40 CFR 122.41 that is representative of the monitored activity. For indirect dischargers subject to pretreatment standards, EPA also assumed weekly monitoring for regulated pollutants. The General Pretreatment Regulation (40 CFR Part 403) establish a minimum monitoring frequency of twice per year (see 40 CFR 403.12 (e)).

Compliance monitoring for cyanide should be performed on a representative number of batches of treated wastewater, taking into consideration the in-situ methods of monitoring the cyanide destruction operation, when the cyanide is being monitored at an in-plant location prior to commingling with other wastewaters. Cyanide sampling must be performed using grab samples and the presence of oxidizing agents must be determined and ascorbic acid added if such agents are present. Each individual grab sample must be preserved in accordance with 40 CFR Part 136.

For most organic pollutants, compositing is required. Compositing requirements are listed in 40 CFR 122.21(4)(viii) which discusses the use of 24-hour composite samples. Facilities may obtain the composite samples by collecting 4 or more grab samples and compositing the samples in the laboratory under chilled conditions by injecting separate aliquots from each grab into the purge cell in the GC/MS instrument. Alternatively, facilities can analyze each grab separately with the composite calculated as the mean of the individual grab samples.

8.3.3 How May Certification of Non-Use of Regulated Chemicals be Achieved?

As indicated in 40 CFR 439.4, permit limits and compliance monitoring are required for each regulated pollutant generated or used at a pharmaceutical manufacturing facility, except where the regulated pollutant is monitored as a surrogate parameter. Permit limits and compliance monitoring are not required for regulated pollutants that are neither used nor generated at the facility. This determination along with recommendations of any surrogates must be submitted with permit applications for approval by the permitting authority and reconfirmed by an annual chemical analysis of wastewater from each monitoring location. Therefore, the list of pollutants for which monitoring would be required should be updated periodically based on consideration of raw materials and process changes throughout the facility. EPA recommends an annual scan for all pollutants listed in Tables 7-1 through 7-5 for direct dischargers, and Tables 7-6 and 7-7 for indirect dischargers. The annual scan should be performed at the compliance monitoring point(s) to identify any regulated pollutants in the wastewater. Permit monitoring and compliance should be required at all monitoring locations for all pollutants detected at any locations. Facilities that do not use a regulated chemical and that can demonstrate a non-detect value for the regulated chemical from their annual scan may certify that they do not use the regulated chemical. In these cases, the facility would not have to monitor for the chemical until an annual scan indicated the presence of the regulated chemical.

8.3.4 What If the Annual Chemical Analysis Scan Identifies Discharge of a Regulated Pollutant Not Covered by a Facility's Permit?

If the annual scan identifies that a regulated pollutant, previously certified as a non-use regulated chemical, is being discharged, then the list of pollutants for which limits and compliance monitoring would be required should be updated. Permits should be developed with a re-opener clause such that identification of pollutants from the annual scan can result in their addition to the permit through a modification.

8.3.5 How May Surrogates Be Used to Demonstrate Compliance?

Facilities discharging more than one regulated organic pollutant within a treatability group may monitor for a single surrogate pollutant if they demonstrate an appropriate degree of control for a specified group of pollutants. (See 40 CFR 439.1(o) and Appendix A) For the purpose of identifying surrogates, pollutants are grouped according to treatability classes. Table 8-1 presents the treatability classes identified for advanced biological treatment which is the BAT/NSPS technology basis for organic pollutant limitations. Table 8-2 presents the treatability classes identified for steam stripping, which is the PSES/PSNS technology basis for organic pollutant limitations. For treatability classes with more than one possible surrogate pollutant, the analyte with the highest concentration or loadings should be chosen as the surrogate pollutant. Plants may monitor for a surrogate pollutant(s) only if they demonstrate that all other

pollutants receive the same degree of treatment. All BAT and NSPS pollutants must go through the same treatment system to use the surrogates listed in Table 8-1. All PSES and PSNS pollutants must go through the same treatment system to use the surrogates listed on Table 8-2.

An individual plant may choose to demonstrate that monitoring is feasible by selecting a given treatability class and maintaining documentation, including flow information and sampling results, that all pollutants in that treatability class receive equivalent treatment. The documentation is then submitted to the permit authority for approval, prior to the reissued or new permit by the permit writer or control authority. It should be noted that participation in a surrogate monitoring program is voluntary on the part of the permittee and must be approved by the permit writer or control authority.

Caution should be taken in selecting surrogate pollutants, as an exceedence of a permit limit for the surrogate pollutant represents an exceedence for all pollutants represented by that surrogate unless appropriate analytical data demonstrate otherwise.

8.3.6 Can Surrogates Be Used if Neither Advanced Biological Treatment Nor Steam Stripping Are Part of the Facility's Treatment System?

If a facility uses a technology other than steam stripping or biological treatment and would like to use surrogates, the permit writer or control authority should request the facility to monitor the facility's technology performance for all applicable regulated pollutants to show the relationship between the treatability of potential surrogate pollutants and that of other pollutants in the wastewater. Based on the performance data, appropriate surrogates can be chosen. The permittee must show equivalent reduction for the pollutants and provide data to show that the pollutant covered by the surrogate will be treated to the same extent that the surrogate is treated. The permit writer or control authority will not want to use pollutants with lower influent concentrations as surrogates because it may be difficult for a facility to demonstrate removal of these surrogates.

8.3.7 What Are the Appropriate Analytical Methods?

Dischargers may use the test methods promulgated at 40 CFR 136.3 or incorporated by reference in the tables of that Part, when available, to monitor pollutant discharges from the pharmaceutical manufacturing industry, unless specified otherwise in Part 439 (See 40 CFR 401.13) or by the permitting authority.

As a part of the final rule, EPA promulgated additional test methods for the pollutants to be regulated under Part 439 for which there are no test methods listed at 40 CFR 136.3. To support the Part 439 regulations at the time of proposal, EPA published test methods developed specifically for the pharmaceutical industry in a compendium entitled, *Analytical Methods for the Determination of Pollutants in Pharmaceutical Manufacturing Industry Wastewater*, EPA-821-B-94-001. These test methods were discussed in the proposed rule and were revised in response to public comment. The revised test methods are available for monitoring some pollutants covered by the final rule. The revised test methods have been published in a revised compendium (*Pharmaceutical Methods Compendium, Revision A*; EPA-821-B-98-016, 1998) with the same title as the proposed compendium.

In addition EPA is allowing use of applicable drinking water methods that have been promulgated at 40 CFR Part 141 and use of ASTM Methods D3371, D3695, and D4763 for monitoring of the regulated pollutants.

Table 8-1: Surrogates for Subpart A/C Direct Dischargers (Biotreatment)

Group	Compound	Surrogate (yes/no)
Alcohols	Ethanol	Yes
	Isopropanol	Yes
	Methanol	Yes
	Phenol	No
	Amyl alcohol	No
Aldehydes	Isobutyraldehyde	No
Alkanes	n-Heptane	Yes
	n-Hexane	Yes
Amides & Amines	Triethylamine	No
	Diethylamine	No
Aromatics	Toluene	Yes
	Xylenes	Yes
	Chlorobenzene	No
	o-Dichlorobenzene	No
	Benzene	No
Chlorinated Alkanes	Methylene chloride	Yes
	Chloroform	Yes
	1,2-Dichloroethane	Yes
Esters & Ethers	Ethyl acetate	Yes
	Tetrahydrofuran	Yes
	Isopropyl acetate	No
	n-Amyl acetate	No
	Isopropyl ether	No
	n-Butyl acetate	No
	Methyl formate	No
Ketones	Acetone	Yes
	MIBK	No
Miscellaneous	Ammonia (aqueous)	No
	Acetonitrile	No
	Dimethyl sulfoxide	No
	Methyl cellosolve	No

Yes - May be a surrogate pollutant for the group.
No - Should not be used as a surrogate pollutant for the group.

Table 8-2: Steam Stripping Surrogates for Indirect Dischargers

Strippability Group	Compound	Surrogate (Yes/No)
High	Methylene Chloride	Yes
	Toluene	Yes
	Chloroform	Yes
	Xylenes	No
	n-Heptane	No
	n-Hexane	No
	Chlorobenzene	No
	Benzene	No
Medium	Acetone	Yes
	Ammonia as N	Yes
	Ethyl acetate	Yes
	Tetrahydrofuran	Yes
	Triethyamine	No
	MIBK	No
	Isopropyl acetate	No
	Diethylamine	No
	1,2-Dichloroethane	No
	n-Amyl acetate	No
	Isopropyl ether	No
	n-Butyl acetate	No
	Methyl formate	No
	Isobutraldehyde	No
	o-Dichlorobenzene	No

Yes - May be a surrogate pollutant for the group.
No - Should not be used as a surrogate pollutant for the group.

In summary, the industrial users may use any of the following analytical methods:

- 40 CFR 136.3, including those incorporated by reference;
- EPA-821-B-94-001;
- 40 CFR 141; and
- ASTM Methods D3371, D3695, and D4763.

Please see *Analytical Methods for the Determination of Pollutants in Pharmaceutical Manufacturing Industry Wastewater,* EPA 821-B-98-016, and *Analytical Methods Guidance for the Pharmaceutical Manufacturing Point Source Category*, EPA 821-B-99-003, for specific information on methods to use and minimum levels. Contact EPA for possible additional methods approved after the publication of this document.

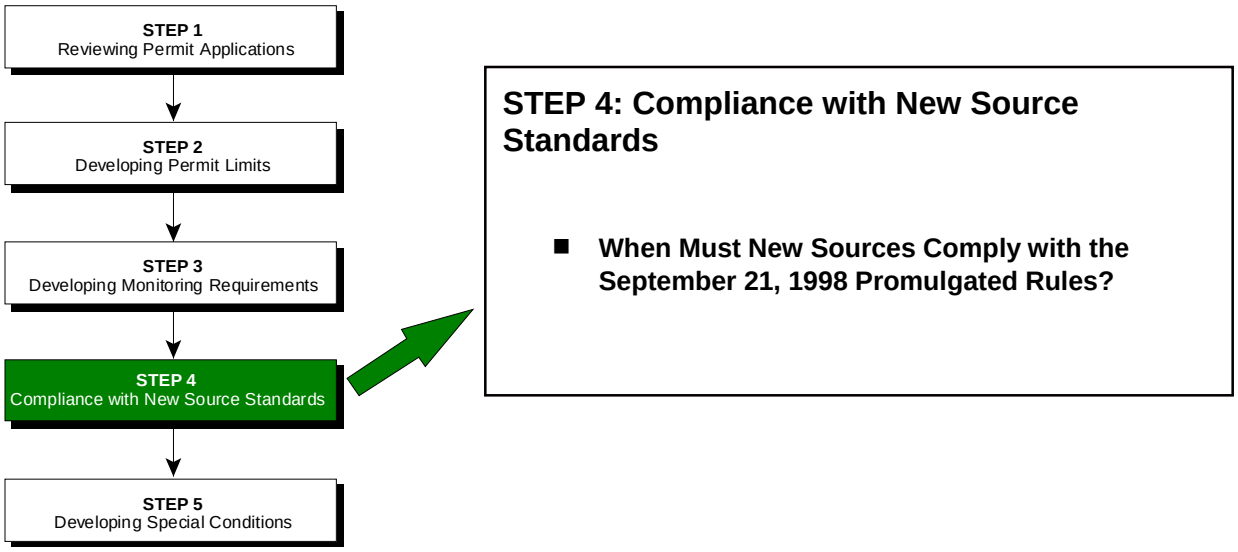
8.3.8 What Is the Level of Detection Required to Demonstrate Compliance?

For various pollutants, EPA has established effluent limitations guidelines and standards that are near the minimum level (ML). The permit authority must require facilities to demonstrate compliance with those limitations and standards using the appropriate methods (which have ML values at or below the specified limitations and standards). Appropriate methods and MLs for each pollutant are listed in *Analytical Methods for the Determination of Pollutants in Pharmaceutical Manufacturing Industry Wastewater,* EPA 821-B-98-016. Facilities cannot demonstrate compliance using an analytical method with an ML above the limitations and standards.

The ML specified for each method is the lowest level at which laboratories calibrate their equipment. To do this, laboratories use standards (i.e., samples at several known concentrations). Calibration is necessary because laboratory equipment does not measure concentration directly, but rather generates signals or responses from analytical instruments that must be converted to concentration values. The calibration process establishes a relationship between the signals and the known concentration values of the standards. This relationship is then used to convert signals from the instruments for samples with unknown concentrations. In the calibration process, one of the standards will have a concentration value at the ML for the pollutant analyzed. Because the ML is the lowest level for which laboratories calibrate their equipment, measurements below the ML are to be reported as <ML.

8.3.9 What Are The Reporting Requirements?

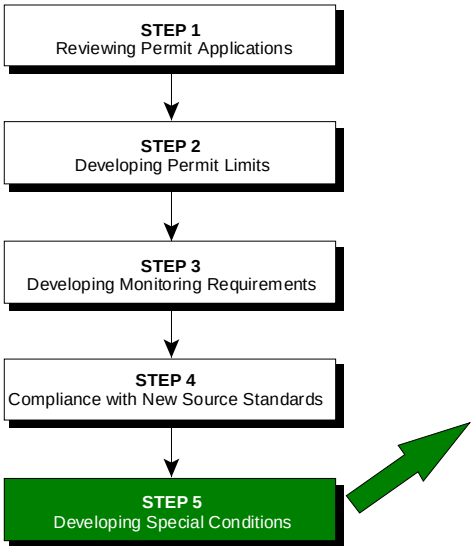
In accordance with Section 122.44(I)(2), the permit authority must require facilities to report the results of compliance monitoring at least once per year. However, the permit authority may require facilities to submit the results more frequently.



8.4 Compliance with New Source Standards

8.4.1 When Must New Sources Comply with the September 21, 1998 Promulgated Rules?

A direct discharging facility which began discharging as a new source subject to the 1983 NSPS on November 21, 1993, for example, is required to be in compliance with the 1998 BCT and BAT regulations after Nov. 21,2003. Compliance for existing source indirect discharging facilities was as soon as possible, but no later than September 21, 2001. Indirect dischargers covered by the 1983 PSNS would then be covered by the September 21, 1998 PSES requirements after September 21, 1998. A new source direct or indirect discharger that commenced discharging after the September 1998 promulgation date must be in compliance with the applicable NSPS or PSNS when they begin discharging.



STEP 5: Developing Special Conditions

- **What are the Special Conditions for Cyanide Limitations?**
- **When is Ammonia Regulated at Indirect Discharging Facilities?**
- **What are the Special Conditions for pH Monitoring?**
- **How Should Permit Writers Account for Nonprocess Wastewater in the Final Effluent?**
- **What is EPA's Guidance with Regard to Coverage of Full Scale Bioengineered Product Manufacturing?**
- **Are Tank Passivating and Electropolishing Wastewaters Considered Metal Finishing Operation Wastewaters Regulated by 40 CFR Part 433?**

8.5 Developing Special Conditions

Permit writers and pretreatment authorities need to be aware of special circumstances involving compliance with the cyanide limitations and standards, ammonia pretreatment standards, pH monitoring, and the portion of nonprocess wastewater in the final effluent.

8.5.1 What Are the Special Conditions for Cyanide Limitations?

In the case of the cyanide limitations and standards, EPA determined that the compliance monitoring point should be in-plant at a point before the cyanide-bearing wastewaters are commingled with noncyanide-bearing waste streams in accordance with EPA permit and pretreatment program regulations. EPA's analysis of waste stream flow data from subpart A and C facilities containing cyanide in their wastewaters indicates that the volume of cyanide-bearing wastewaters is, on average, less than 2.1 percent of the total process wastewater flow and that all but two of the facilities required to monitor for cyanide do so at an in-plant monitoring point. However, facilities that can demonstrate that it is feasible to monitor for cyanide at the end-of-pipe point may do so.

8.5.2 When Is Ammonia Regulated at Indirect Discharging Facilities?

In connection with the ammonia pretreatment standards promulgated for subparts A and C, EPA has determined that the pollutant ammonia does not pass through POTWs that possess nitrification capability. As a result, ammonia pretreatment standards would not apply to subpart A and C industrial users that discharge to these POTWs. POTWs (including those with nitrification) may impose more stringent local limits for ammonia.

8.5.3 What Are the Special Conditions for pH Monitoring?

During the post-proposal period, EPA received comments from industry commenters that complying with the pH requirements 100% of the time when using continuous monitoring is not practical for many facilities. Direct discharging pharmaceutical facilities are supposed to maintain effluent pH in the 6.0-9.0 range. The general pretreatment regulations at 40 CFR 403.5(b)(2) set a pH minimum of 5.0, except in certain design conditions, but do not set an upper boundary. EPA has addressed the problem of random excursions at 40 CFR 401.17 for direct discharging facilities. This regulation recognizes that random excursions from the pH range (6.0-9.0) may occur in the process of continuous monitoring and these random excursions should not be treated as violations. Currently, there is no similar provision for indirect dischargers.

8.5.4 How Should Permit Writers Account for Nonprocess Wastewater in the Final Effluent?

In implementing the final limitations and standards, permit writers need to account for the facility's nonprocess wastewater contained in the effluent being discharged in developing either mass or concentration based permit limits. As discussed previously, the final limitations and standards for direct dischargers and for indirect dischargers with respect to ammonia when biological treatment is used are developed from data sets from plants which had less than 25% nonprocess wastewater in the total plant discharge. Examples are presented in the next section which show how to incorporate facility flow with dilution water.

8.5.5 What Is EPA's Guidance with Regard to Coverage of Full Scale Bioengineered Product Manufacturing?

At the time the final regulations were developed, full-scale bioengineering activities had not been evaluated and the manufacture of bioengineered products was not addressed in the documents supporting the final regulation. Bioengineering activities at the time, which were considered to be subpart E (research) activities, were discussed in a response to three different comments. The basis for the response was information obtained during an engineering site visit to a pharmaceutical manufacturing plant which was engaged in bioengineering related activities. EPA's position with regard to these small scale laboratory or bench scale research or manufacturing activities was that they did not involve generation of significant quantities of wastewater and/or pollutants and the disposal of wastewater containing bioengineered microorganisms was addressed by guidance from the National Institutes of Health (NIH). Therefore, coverage of these wastewaters at research facilities by the final pharmaceutical manufacturing rule was not deemed appropriate as noted in comment responses.

Since the final pharmaceutical manufacturing regulations were promulgated on Sept. 21, 1998, pharmaceutical and other manufacturers have begun producing bioengineered products using bioengineering techniques developed from bench scale research operations. In manufacturing these bioengineered pharmaceutical products, various facilities have used processes that are similar to the fermentation process more generally defined in 40 CFR 439.11 and described in the Development Document. In some cases, the processes generate wastewater in quantities comparable to that generated by fermentation operations described in the Development Document but do not utilize solvents in the operation. In still other cases, non-pharmaceutical manufacturers such as pesticide active ingredient manufacturers have used the same kind of manufacturing to produce pesticide active ingredients. However, because of restrictive definition of fermentation in Part 439, in EPA's view, the fermentation subcategory does not include the manufacture of bioengineered products.

It may be argued by permit applicants and industrial users that not covering bioengineering research activities that were in place at the time the rule was promulgated provides a blanket exclusion for all bioengineering related manufacturing operations. However, such an interpretation ignores the facts that EPA's exclusion with regard to bioengineering activities conducted prior to promulgation was based on

the following: (1) the wastewater and/or pollutants generated from these operations was considered insignificant; and (2) the disposal of wastewater containing bioengineered microorganisms from these operations was addressed in guidance from the National Institutes of Health (NIH) and EPA did not revise the subpart E (research) requirements in the 1998 rule. In addition, EPA indicated in the preamble to the final regulations that the wastewaters from these operations were not evaluated or characterized by EPA prior to promulgation of the final rule.

In EPA's view, product classification and wastewater characteristics should determine whether limitations similar to those in the pharmaceutical rule apply to wastewater from a bioengineering process. If a product is similar to those regulated in 40 CFR 439.0 and the wastewater generated during its production is similar in quantity and quality to wastewater generated by one of the four manufacturing subcategories, then permit writers may consider developing appropriate limitations on a BPJ basis for the manufacturing wastewater.

8.5.6 Are Tank Passivating and Electropolishing Wastewaters Considered Metal Finishing Operation Wastewaters Regulated by 40 CFR Part 433?

The metal finishing operation regulations in 40 CFR Part 433 covering wastewaters generated by tank passivation and/or electropolishing are not meant to be applied to insignificant process sources that are coincidental to the metal finishing industry and are not related to metal finishing products. Therefore, passivation and/or electropolishing wastewaters periodically generated in tank cleaning at pharmaceutical manufacturing facilities are not covered by 40 CFR Part 433. If a POTW pretreatment authority identifies a concern over metals that could be contained in any spent passivation or electropolishing solution and rinse, the authority may require the facility generating such wastewaters to hold the solution on site until it can be analyzed for metals and discharged according to the results.

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.

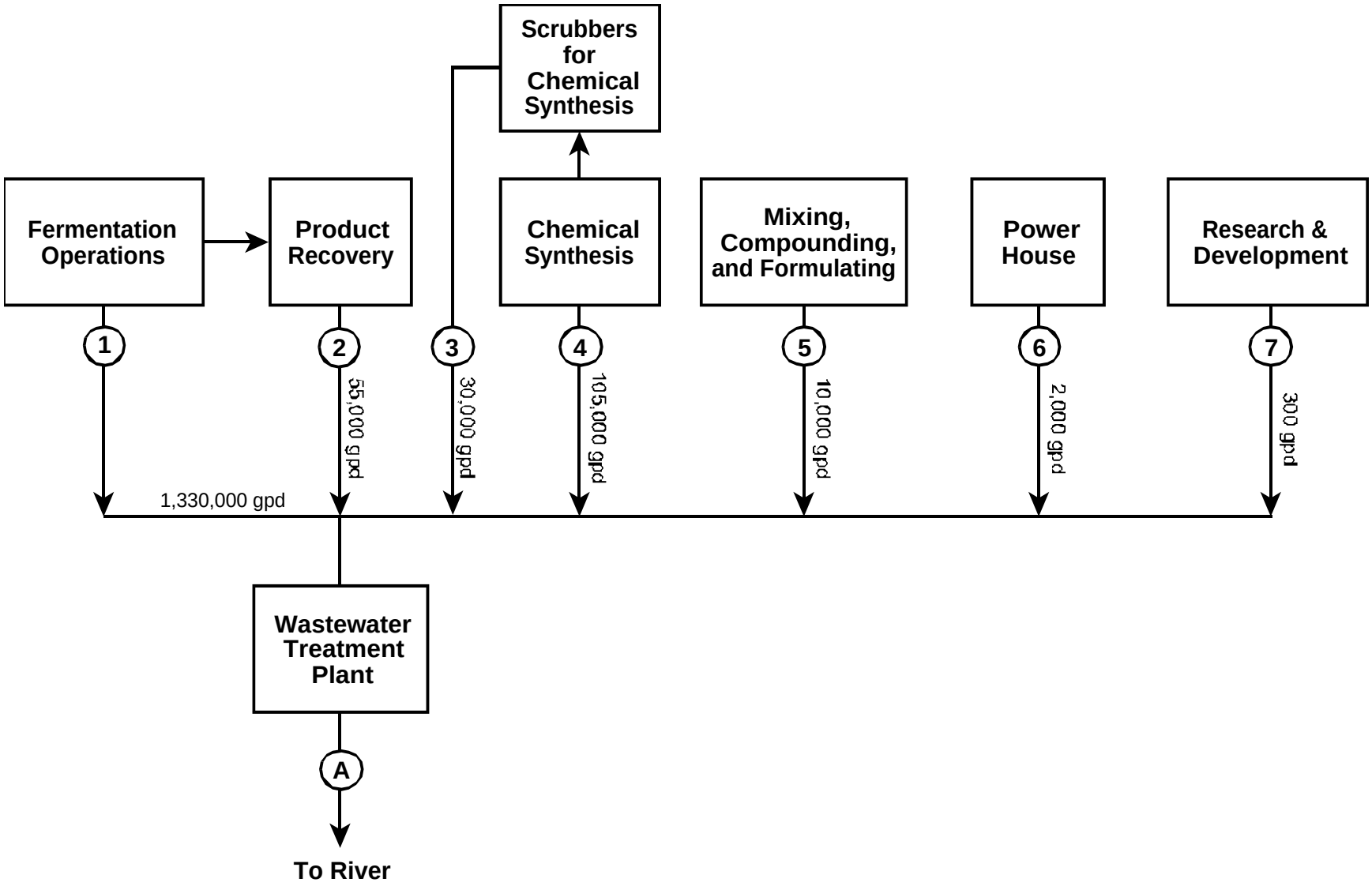


Figure 9-1: Flow Schematic for Facility A

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.

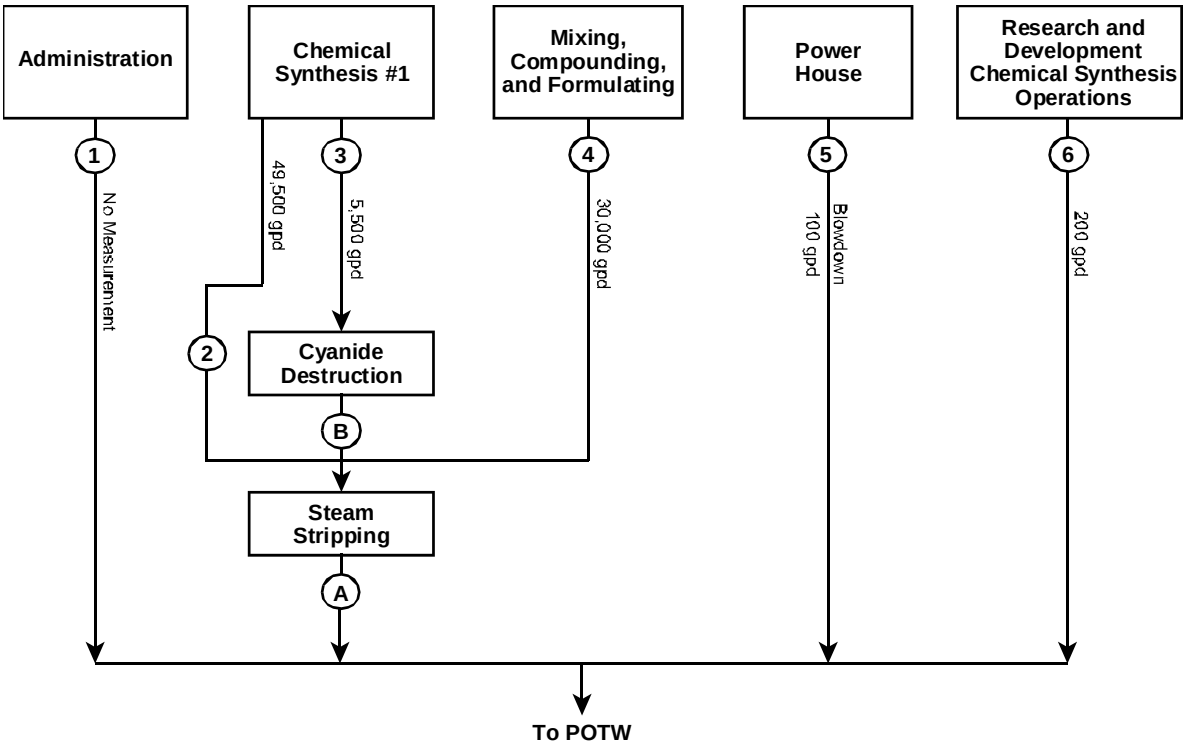


Figure 9-2: Flow Schematic for Facility B

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.

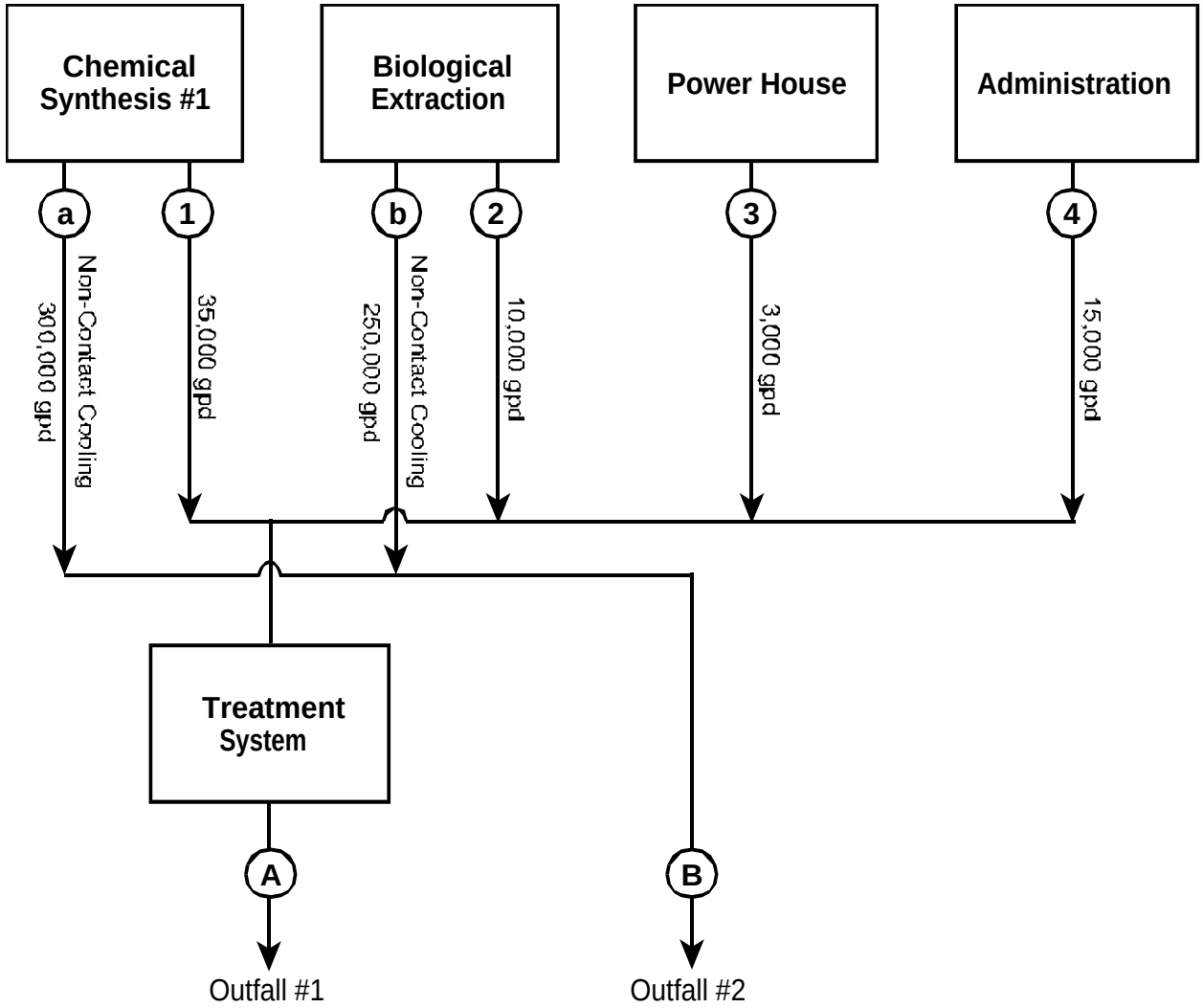


Figure 9-3: Flow Schematic for Facility C

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.

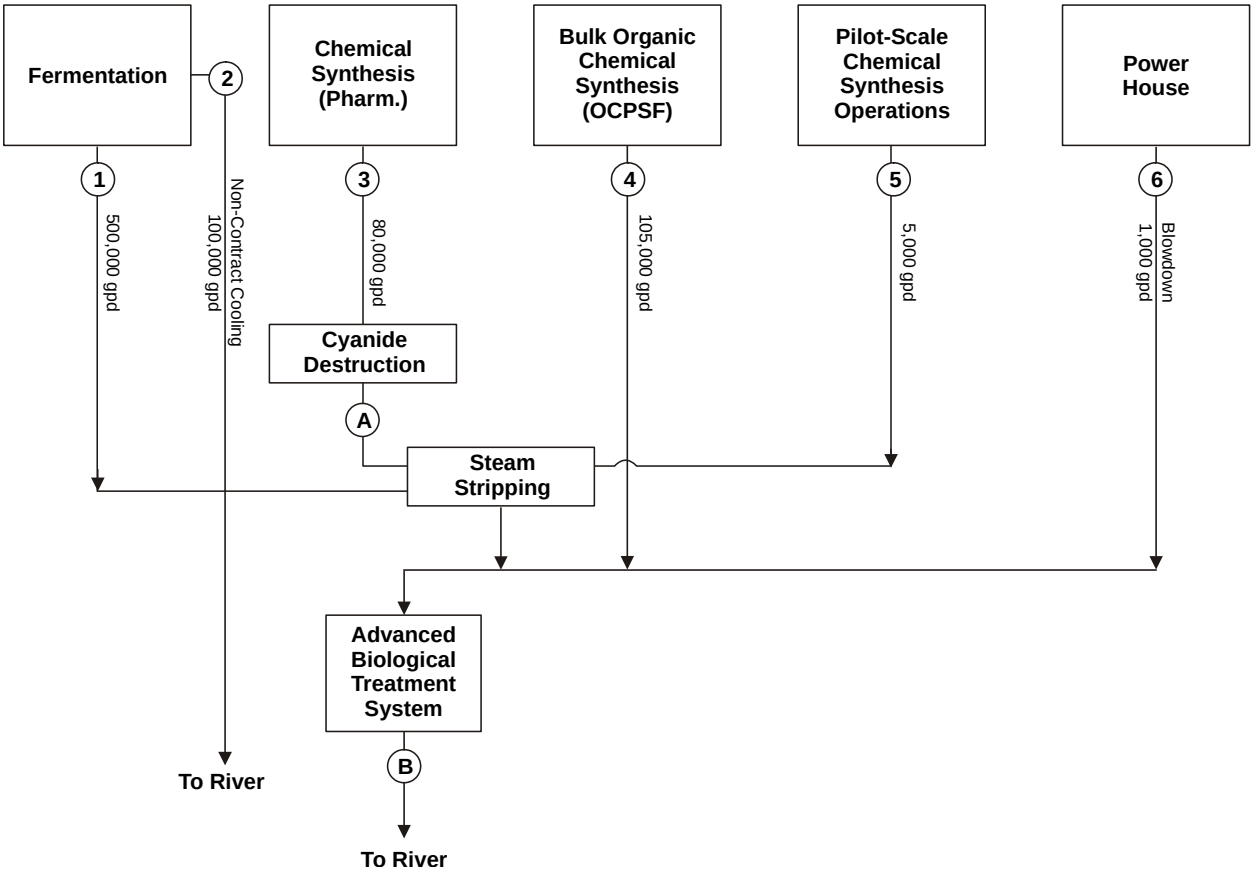


Figure 9-4: Flow Schematic for Facility D

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.

10. Where to Get Additional Help

This section presents additional sources of information, as well as EPA contacts, that may help permit writers and control authorities obtain additional information related to implementation of the final pharmaceutical effluent limitations guidelines and standards for subparts A, B, C, D, and E. Specifically, this section presents a list of selected documents, databases, and websites either relating generally to the pharmaceutical industry, or specifically to the September 21, 1998 Promulgated Rule. These lists also include information on how to reach EPA program personnel and how to access these information sources.

Questions specifically related to the effluent limitations guidelines and standards for the pharmaceutical industry should be directed to:

Headquarters:

Meghan Hessenauer
Engineering and Analysis Division
Office of Water
U.S. EPA
1200 Pennsylvania Ave., NW
Washington, DC 20460
Email: hessenauer.meghan@epa.gov

Regional Contacts:

Region 1
Justin Pimpare
1 Congress Street, Suite 1100
Boston, MA 02114-2023
Email: pimpare.justin@epa.gov

Region II
Jacqueline Rios
290 Broadway
New York, NY 10007-1866
Email: rios.jacqueline@epa.gov

Region IV
Dee Stewart
61 Forsyth Street, S.W.
Atlanta, GA 30303-8960
Email: stewart.dee@epa.gov

Region V
Matthew Gluckman
77 West Jackson Boulevard
Chicago, IL 60604-3507
Email: gluckman.matthew@epa.gov

Region IX
Keith Silva
75 Hawthorne Street
San Francisco, CA 94105
Email: silva.keith@epa.gov

10.1 Information Relating to the Pharmaceutical Rule

This manual is one element in a broad spectrum of materials that are available related to the regulations promulgated September 21, 1998 for pharmaceutical manufacturing facilities with operations in subparts A, B, C, D, and E. Figure 10-1 illustrates some of the information resources currently available.

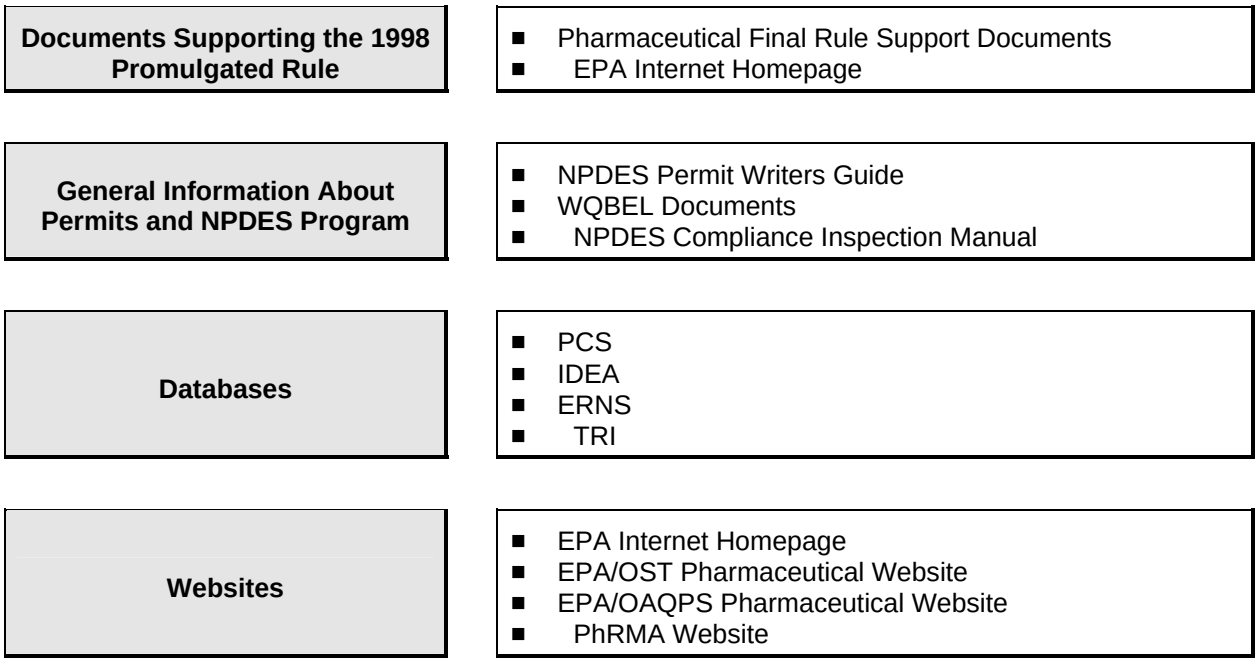


Figure 10-1: Information Resources Map

10.1.1 Documents Supporting the 1998 Promulgated Rule

- *Development Document for Effluent Limitations Guidelines and Standards for the Pharmaceutical Manufacturing Point Source Category*, EPA-821-R-98-005, July 1998.
- *Environmental Assessment of the Final Effluent Limitations Guidelines and Standards for the Pharmaceutical Manufacturing Industry*, EPA 821-B-98-008, July 1998.
- *Statistical Support Document for Final Effluent Limitations Guidelines and Standards for the Pharmaceutical Manufacturing Industry*, EPA 821-B-98-007, July 1998.
- *National Emission Standards for Hazardous Air Pollutants for the Pharmaceutical Manufacturing Industry; Summary of Public Comments and Responses*, EPA 450-R-98-002, July 1998.

10.1.2 General Information About Permits and NPDES Program

- *NPDES Permit Writer's Manual*, EPA-833-B-96-003. This 1996 EPA manual was prepared to provide the basic regulatory framework and technical considerations that support the development of wastewater discharge permits as required under the NPDES program.

- *NPDES Compliance Inspection Manual*, EPA 305-X-03-004, July 2004. This EPA manual was developed to support personnel that conduct NPDES inspections of wastewater treatment plants, industrial storm water and construction site dischargers, pretreatment facilities, biosolids handling and treatment facilities, Concentrated Animal Feeding Operations, municipal wastewater collection systems, as well as pollution prevention and multimedia concerns. The manual presents standard procedures for inspections and specific technical information necessary to conduct the full range of NPDES compliance inspection activities. This document is available from EPA's Web site at: **http://www.epa.gov/compliance/resources/publications/monitoring/inspections/npdesinspect/index.html**

- *Guidance for Water Quality-Based Decisions: The TMDL Process*, EPA-440-4-91. This document is intended to define and clarify the requirements under Section 303(d) of the Clean Water Act. Its purpose is to aid state water-quality program managers in understanding the application of total maximum daily loads within the water quality-based approach to establish pollution control limits for waters not meeting water quality standards.

- *Technical Support Document for Water Quality-Based Toxics Control*, EPA/505/2-90-001. This document was prepared as technical guidance for assessing and regulating the discharge of toxic substances to waters of the United States.

- *Industrial User Permitting Guidance*, EPA#833R89001, September 1989.

10.1.3 Databases

- **PCS.** The Permit Compliance System (PCS) is a national information system that automates entry, updating and retrieval of NPDES data and tracks permit issuance, permit limits, and monitoring data for NPDES facilities. Public access is available by obtaining a mainframe account on EPA's National Computer Center. See **http://www.epa.gov/compliance/data/systems/index.html** for further details.

- **IDEA.** The Integrated Data for Enforcement Analysis System (IDEA) is an interactive data retrieval and integration system developed by EPA's Office of Enforcement and Compliance Assurance. Users can retrieve data for performing multimedia analyses of regulated facilities, produce compliance histories of individual facilities, identify a group of facilities that meet user-defined criteria, and produce aggregated data on selected industries. Public access is available by obtaining a mainframe account on EPA's National Computer Center. See **http://www.epa.gov/compliance/data/systems/index.html** for further details.

- **ERNS.** Through The Emergency Response Notification System, EPA maintains a database of reported spills of oil and other materials. See **http://www.epa.gov/compliance/data/systems/waste/index.html** for further details.

- **TRI Data.** The Toxics Release Inventory (TRI) provides the public with information on toxic chemicals being used, manufactured, transported, or released into the environment.

See **http://www.epa.gov/opptintr/tri** for access to numerous TRI topics, including; "What is TRI", "Accessing and Using TRI Data", "Tri Forms and Reporting Requirements", "TRI chemicals", "TRI Program Development", "TRI National and International Programs", "TRI Contacts", and "What's New with TRI". See **http://www.epa.gov/opptintr/tri/ttpubacc.htm** to learn more about TRI information found on CD-ROM, the Right-to-Know Network (RTK NET), Envirofacts, TOXNET (user fee), and TRI User Support (TRI-US).

10.1.4 Websites

- **EPA on the World Wide Web.** EPA's webserver is the primary public access mechanism on the Internet for EPA. The webserver provides a range of EPA-generated information in electronic format, and also offers access to EPA's Online Library Service (OLS), the national online catalog of the EPA library network. It includes the catalogs of the Headquarters Information Resource Center and all the Regional libraries.

  Via Internet:
  EPA's homepage on the World Wide Web: **http://www.epa.gov**
  EPA's pharmaceutical rulemaking actions homepages on the World Wide Web:
  http://www.epa.gov/ost/guide/pharm (water documents)
  http://www.epa.gov/ttn/oarpg (air documents)

10.2 Other Sources and Contacts

10.2.1 EPA Headquarters Information Resource Center

The EPA Headquarters Information Resource Center provides information support services to EPA staff and maintains a varied collection of environmental resources, including CD-ROMs, an online catalog, and other program-specific services. The library provides services to the general public and develops several publications, including newsletters and brochures. Library hours are 8:00 a.m. to 5:00 p.m. ET, Monday through Friday. EPA's Online Library Service (OLS) is available through Telnet: "epaibm.rtpnc.epa.gov."

10.2.2 National Technical Information Service (NTIS)

Located in the U.S. Department of Commerce, the National Technical Information Service (NTIS) is the central source for the public sale of U.S. Government-sponsored research, development, and engineering reports. It is also a central source of federally generated machine processible data files. It contains reports on air pollution, acid rain, water pollution, marine pollution, marine ecosystems, land use planning, fisheries management, solar energy, offshore oil drilling, solid wastes, traffic noise, and radiation monitoring.

For more information, contact:
Chief, Order Processing Branch
National Technical Information Service
5285 Port Royal Road
Springfield, Virginia 22161
Tel: (703) 487-4650
Fax: (703) 321-8547

Appendix A Glossary

Biochemical oxygen demand (BOD_5) - Five-Day Biochemical Oxygen Demand. A measure of biochemical decomposition of organic matter in a water sample. It is determined by measuring the dissolved oxygen consumed by microorganisms to oxidize the organic contaminants in a water sample under standard laboratory conditions of five days at 20°C. BOD_5 is not related to the oxygen requirements in chemical combustion.

Chemical oxygen demand (COD) - A bulk parameter that measures the oxygen-consuming capacity of organic and inorganic matter present in water or wastewater. It is expressed as the amount of oxygen consumed from a chemical oxidant in a specific test.

Continuous discharge - Discharge that occurs without interruption throughout the operating hours of the facility.

Conventional pollutants - The pollutants identified in sec. 304(a)(4) of the CWA and the regulations thereunder (biochemical oxygen demand (BOD_5), total suspended solids (TSS), oil and grease, fecal coliform, and pH).

Daily discharge - The discharge of a pollutant measured during any calendar day or any 24-hour period that reasonably represents a calendar day. For pollutants with limitations expressed as mass, the daily discharge is calculated as the total mass of the pollutant discharged over the day. For pollutants with limitations expressed in other units of measurement, the daily discharge is calculated as the average measurement of the pollutant over the day.

Direct discharger - A facility that discharges or may discharge treated or untreated process wastewaters, non-contact cooling waters, or non-process wastewaters (including stormwater runoff) into waters of the United States.

Effluent limitation - Any restriction, including schedules of compliance, established by a State or the Administrator on quantities, rates, and concentrations of chemical, physical, biological, and other constituents which are discharged from point sources into navigable waters, the waters of the contiguous zone, or the ocean.

End of the pipe - The point at which final facility effluent is discharged to waters of the United States or introduced to a POTW.

Final effluent - Facility wastewater discharges to receiving waters including streams, lakes, and other waters of the U.S.

Indirect discharger - A facility that discharges or may discharge wastewaters into a publicly owned treatment works or a treatment works not owned by the discharging facility.

Influent - Facility wastes, water, and other liquids, which can be raw or partially treated, flowing into a treatment plant, reservoir, basin, or holding pond.

Maximum daily discharge limitation - The highest allowable daily discharge of a pollutant measured during a calendar day or any 24-hour period that reasonably represents a calendar day.

Minimum level (ML) - The level at which the analytical system gives recognizable signals and an acceptable calibration point.

Non-continuous discharge - Discharge that occurs only during specific periods of time (seasons, or operating shift variations). Does not apply to treatment plant or process upset conditions; periods of no discharge are at least 24 hours in duration.
Nonconventional pollutants - Pollutants that are neither conventional pollutants nor toxic pollutants (see 40 CFR Sections 401.15, 401.16 and Part 423, Appendix A).

NPDES - National Pollutant Discharge Elimination System. The NPDES program is authorized by the Clean Water Act and requires permits for the discharge of pollutants from any point source into waters of the United States.

POTW - Publicly-owned treatment works as defined at 40 CFR 403.3(o).

Pretreatment standard - A regulation addressing industrial wastewater effluent quality required for discharge to a POTW.

Process water - Water used to dilute, wash, or carry raw materials and any other materials used in the manufacturing process.

Toxic pollutants - Pollutants designated as toxic pursuant to Section 307(a)(1) of the Act and listed in 40 CFR Section 401.15.

Wastewater - Water carrying waste materials from a facility. It is a mixture of water, and dissolved and suspended pollutants.

Waters of the United States - As defined in 40 CFR 122.2. This definition includes all waters that are currently used, may be used in the future, or were used in the past, in interstate or foreign commerce (including all waters subject to the ebb and flow of the tide) and adjacent wetlands.