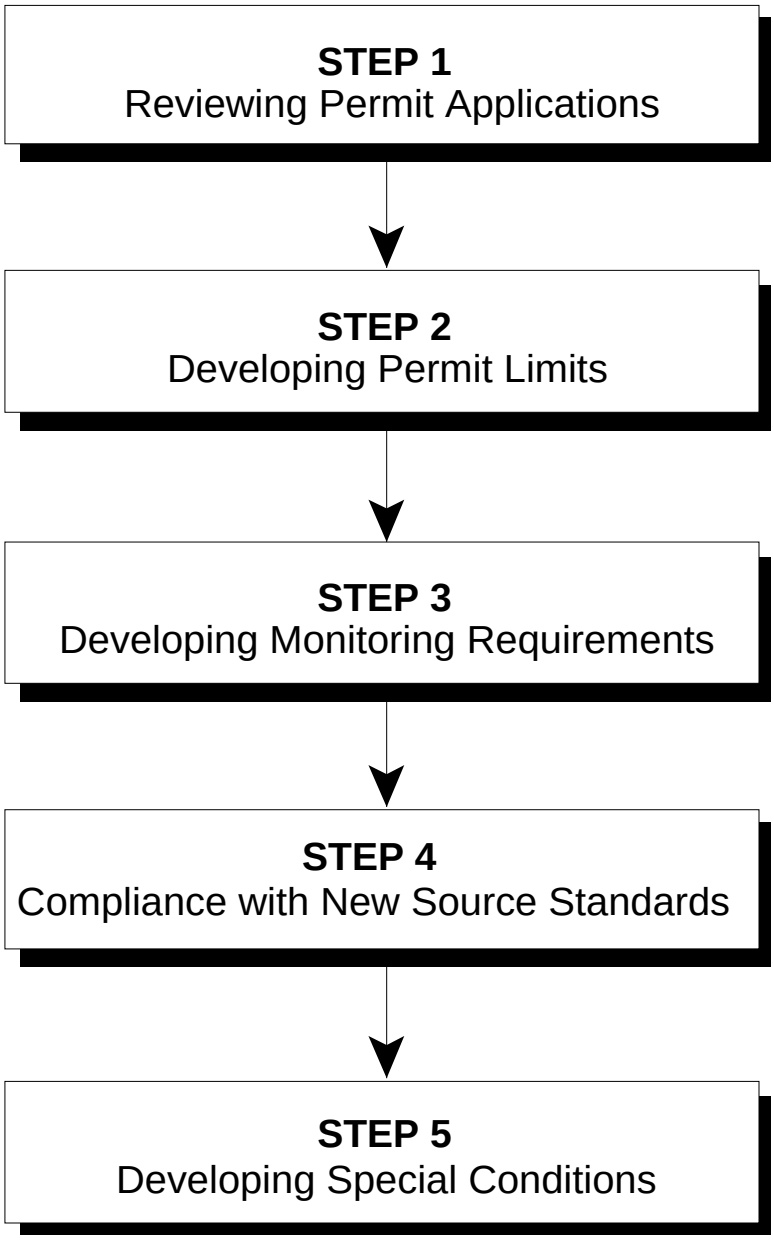
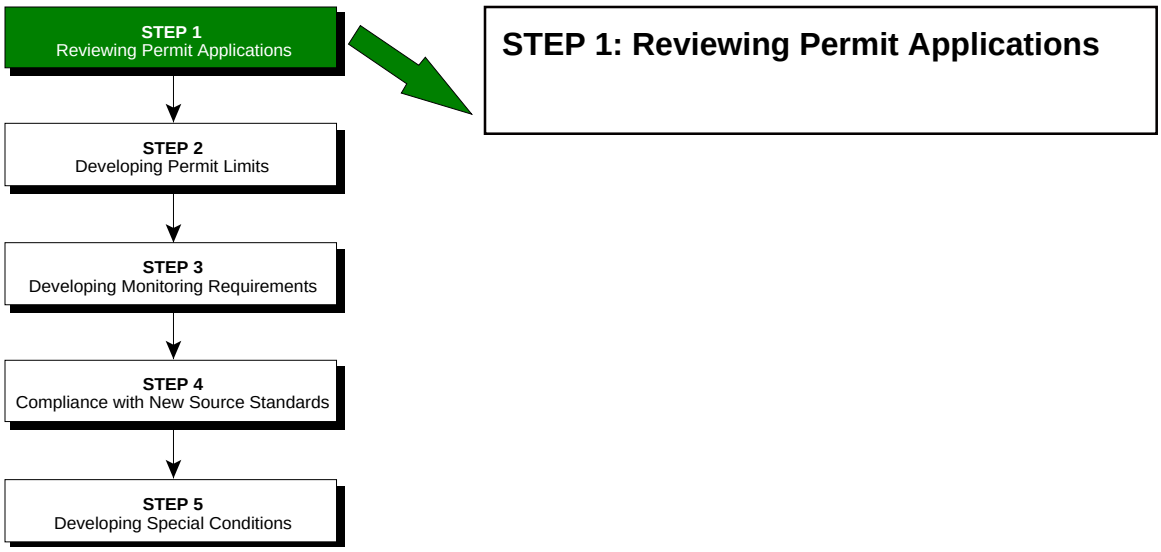
How Are Permits Developed for Facilities with Operations in Subparts A, B, C, D, and E?

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:





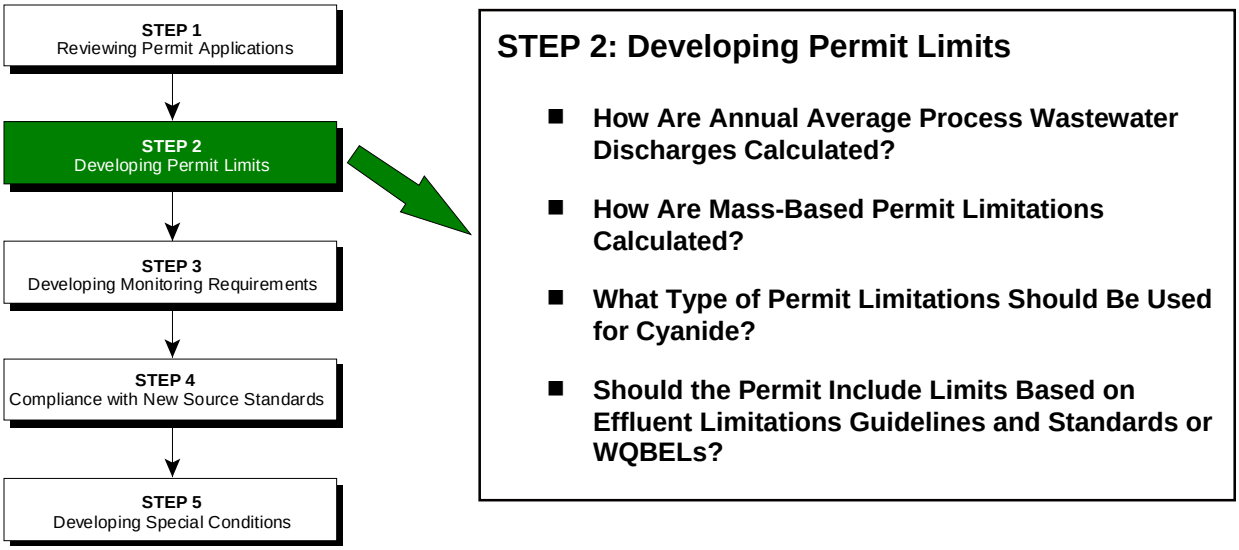
8.1 Reviewing Permit Applications

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:

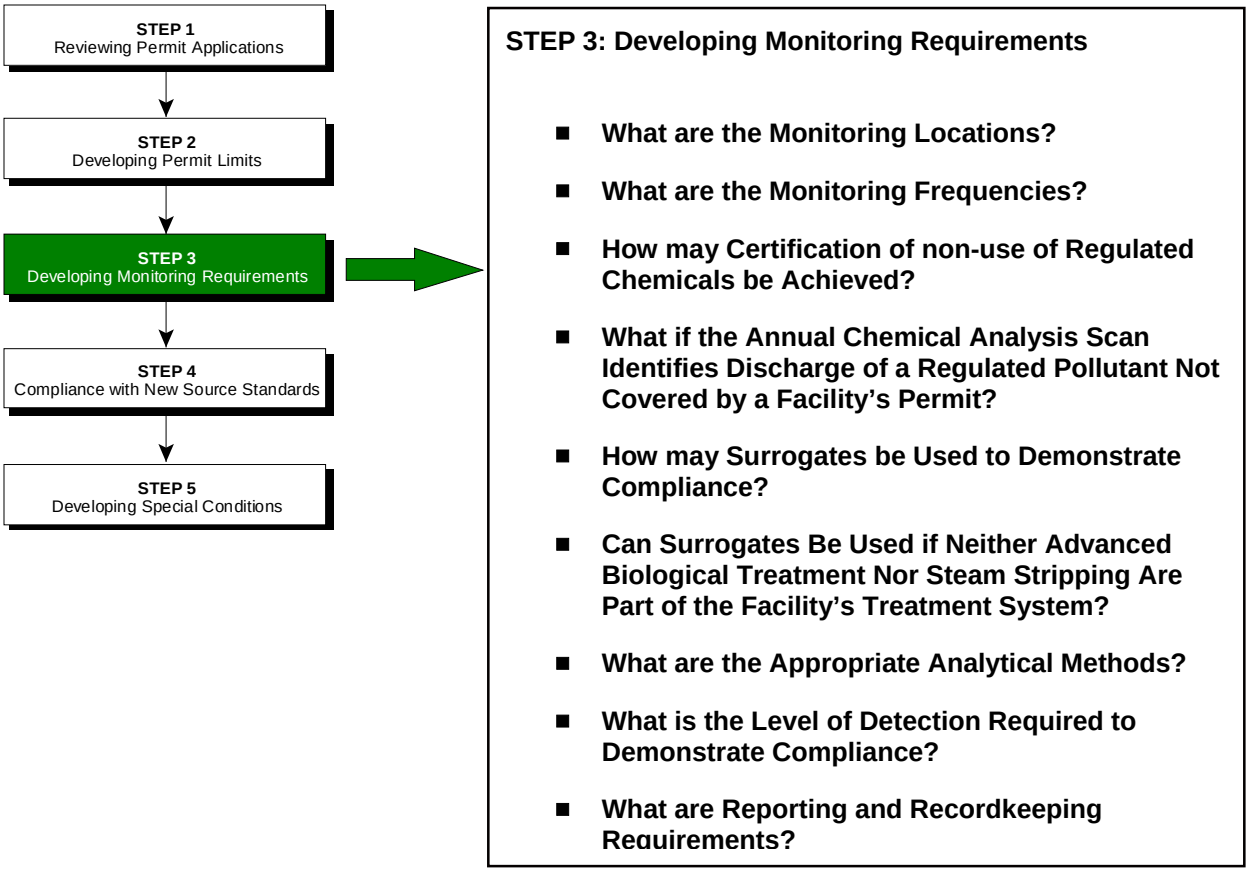
$$k_2 = \frac{1\ \text{L}}{0.264179\ \text{gal}} \times \frac{1\ \text{g}}{1{,}000{,}000\ \mu\text{g}} \times \frac{1\ \text{lb}}{453.592\ \text{g}} = 8.345 \times 10^{-9} \times \frac{\text{L lb}}{\text{gal}\ \mu\text{g}}$$

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.

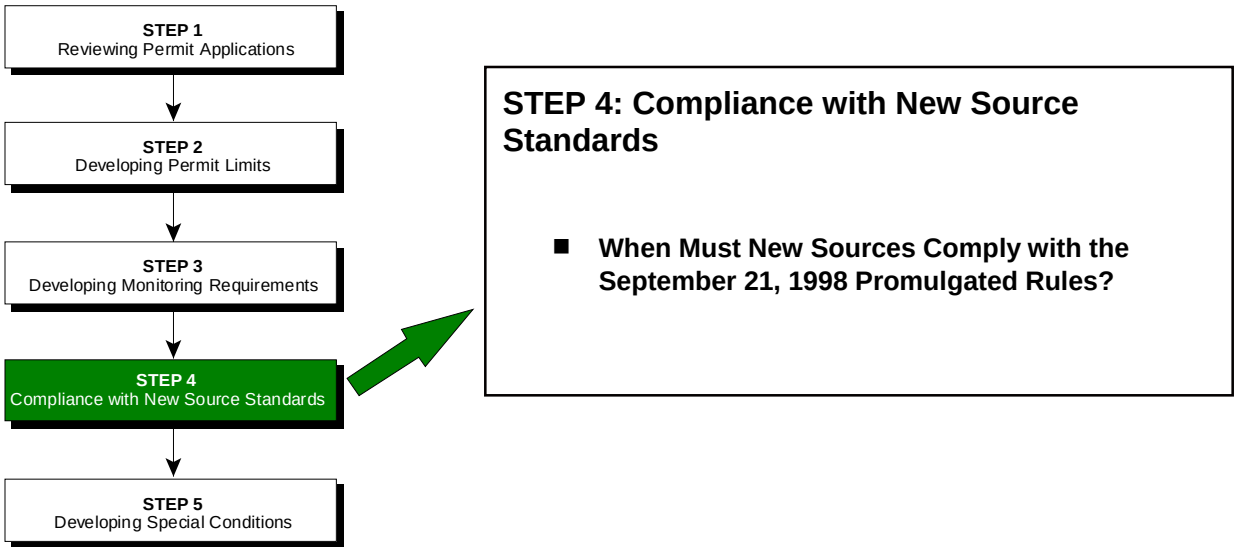
8.3.8 What Is the Level of Detection Required to Demonstrate Compliance?

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?

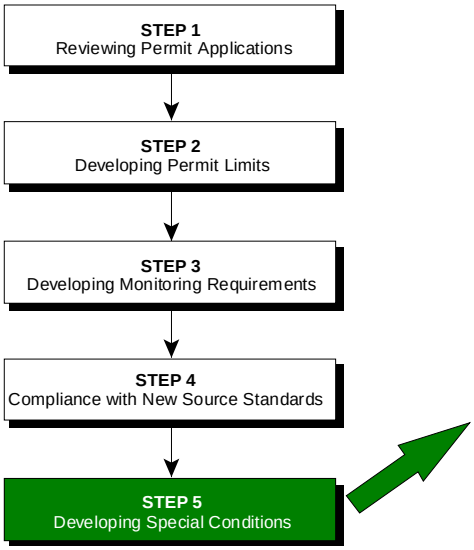
In accordance with Section 122.44(I)(2), the permit authority must require facilities to report the results of compliance monitoring at least once per year. However, the permit authority may require facilities to submit the results more frequently.



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.