

SECTION 13

BEST PRACTICABLE CONTROL TECHNOLOGY (BPT)

13.1 Introduction

Effluent limitations guidelines based on the best practicable control technology currently available establish quantitative limits on the direct discharge of pollutants from existing industrial point sources. BPT effluent limitations guidelines are based upon the average of the best existing performance, in terms of treated effluent discharged by facilities of various sizes, ages, and unit processes within a category or subcategory. BPT effluent limitations guidelines most commonly focus on the control of conventional and nonconventional pollutants, but can also control priority pollutants, such as cyanide.

BPT effluent limitations guidelines are based upon the performance of specific technologies, but do not require the use of any specific technology. BPT effluent limitations guidelines are applied to individual facilities through NPDES permits issued by EPA or authorized states under Section 402 of the CWA. The facility then chooses its own approach to comply with its permit limitations.

In developing BPT, the Agency considered the total cost of applying the technologies in relation to the effluent reduction benefits achieved from the technologies; the size and age of equipment and facilities; the processes used; the engineering aspects of applying various types of control techniques; process changes; and nonwater quality environmental impacts, including energy requirements.

The BPT effluent limitations are based on advanced biological treatment for Subcategories A, B, C, and D, as discussed in Section 11.

The following information is discussed in this section:

- Section 13.2 reviews the subcategories and the pollutants to be regulated by BPT and presents the final BPT effluent limitations guidelines; and
- Section 13.3 discusses BPT effluent limitations guidelines implementation with regard to NPDES permits, point of application, and monitoring and compliance issues.

13.2 Summary of the BPT Effluent Limitations Guidelines

13.2.1 Regulated Subcategories

BPT effluent limitations guidelines, as discussed in Section 7.3, are for Subcategories A, B, C, and D direct dischargers. As discussed in Section 4.3, Subcategories A, B, and C include wastewater discharges resulting from the manufacture of pharmaceuticals by fermentation, biological or natural extraction processes, and chemical synthesis processes, respectively. Subcategory D includes wastewater discharges resulting from mixing, compounding, and formulating of pharmaceutical products.

13.2.2 Regulated Pollutants

Since the BPT guidelines were last revised in 1983, there have been significant improvements in secondary treatment. Therefore, it is appropriate to revise the BPT limitations to reflect the best practicable control technology currently available.

The BPT effluent limitations guidelines revise COD effluent limitations for Subcategories A, B, C, and D. Raw wastewaters from pharmaceutical facilities are characterized by high COD concentrations. EPA found a correlation between effluent COD and aquatic toxicity in the 1987 pilot-plant carbon study which was conducted on pharmaceutical industry wastewaters. Also, COD loads can deplete oxygen levels in the water resulting in adverse health effects in fish, including mortality, and reduction in biological diversity. EPA previously promulgated COD

limits of minimum 74% removal, however, facilities can meet this limitation while still discharging effluents with high COD levels.(3)

Under the revised BPT COD regulations, facilities must comply with the new COD concentration limitations, promulgated with this rulemaking, or the 74% reduction of COD, whichever is more stringent.

The revised BPT in this rulemaking clarifies existing in-plant cyanide limitations for Subcategory A and C facilities. Compliance monitoring for cyanide should occur immediately after cyanide destruction, before commingling cyanide-bearing wastestreams with non-cyanide-bearing wastestreams, unless a facility can demonstrate that cyanide is detectable at end-of-pipe. The 1983 cyanide limitations for Subcategory B and D direct dischargers are being withdrawn; these subcategories do not use or generate cyanide.

The BPT effluent limitations guidelines for BOD₅ and TSS have not been revised, however, revision of the BPT effluent limitations guidelines for COD will achieve incidental removals of BOD₅ and TSS. However, the incidental removal of TSS is expected to be significantly less than the incidental removal of BOD₅ as a result of the new COD limitations. The BOD₅ effluent limitations, expressed as mass loading, require a minimum 90% reduction in the long-term average daily BOD₅ load of the raw (untreated) process wastewater, multiplied by a variability factor of 3.0. The effluent limitation for TSS, expressed as a mass loading, must be calculated as 1.7 times the BOD₅ limitation. The pH effluent limit, established in the 1976 Final Rule (41 FR 50676) to be the range of 6.0 to 9.0 standard units for all subcategories, will not be amended. As discussed in Section 6.5, other conventional pollutants, such as fecal coliform and oil and grease, will not be regulated under BPT, because they are not pollutants of concern for this industry.

13.2.3 The BPT Effluent Limitations Guidelines

The BPT effluent limitations guidelines for each subcategory are based on a combination of long-term mean effluent concentrations and variability factors that account for day-to-day variation in

measured treated effluent concentrations. Long-term means, discussed in Section 8, are target values that a facility's treatment system should achieve on a long-term, average basis. The variability factors, discussed in the Statistical Support Document(1), located in the Administrative Record for this rulemaking, represent the ratio of an elevated value, expected to occur only rarely, to the long-term mean. The purpose of the variability factor is to allow for variations in effluent concentrations that comprise the long-term mean. A facility that designs and operates its treatment system to achieve a long-term mean on a consistent basis should be able to comply with the daily and monthly limitations in the course of normal operations.

Table 13-1 presents the maximum daily and monthly average BPT effluent limitations guidelines for end-of-pipe monitoring points for Subcategories A, B, C, and D based on long-term mean treatment performance concentrations and associated variability factors.

The limitations for COD were calculated using available data sets from best-performing advanced biological treatment systems. The long-term mean concentration was multiplied by the 1-day and 30-day variability factors for each data set. This resulted in data set specific limitations. The mean value of the dataset specific limitations based on the 1-day variability factor is the BPT maximum limitation for any one day; the mean value based on the 30-day variability factor is the BPT monthly average limitation.

13.3 Implementation of the BPT Effluent Limitations Guidelines

13.3.1 NPDES Permit

BPT effluent limitations guidelines are applied to individual facilities through NPDES permits issued by EPA or authorized states under Section 402 of the CWA.

The effluent limitations guidelines are concentration-based and, as such, do not regulate wastewater flow. For end-of-pipe effluent limitations, permit writers will use a reasonable estimate of process wastewater discharge flow allowing for up to 25 percent non-process 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 by 40 CFR 122.2 to include wastewaters resulting from manufacture of pharmaceutical products 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 end-of-pipe limitations are developed from performance data at facilities which contain less than 25 percent nonprocess water through their biological treatment facility. Therefore, the end-of-pipe limitations for BPT apply to the pharmaceutical process wastewater allowing for up to 25 percent nonprocess wastewater. Nonprocess flow in excess of 25 percent should be handled separately in establishing permit limits.

Using current facility information provided by the permit applicant, the permitting or control authority must determine the appropriate wastewater discharge flow to use when developing mass based limitations. In cases where the permit writer deems the wastewater discharge flow claimed by industry to be excessive, he/she may develop a more appropriate process wastewater discharge flow for use in computing the mass effluent limitations. The permit writer should review the following items to evaluate whether process wastewater discharge flow is excessive.

- Component flows, to ensure that the claimed flows are, in fact, process wastewater discharge flows as defined by 40 CFR 122.2.
- 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 an NPDES permit for a direct discharger, the permit writer should determine the facility's subcategorization and use the corresponding concentration-based effluent limitations as a basis for developing the mass-based limitations. The permit writer should then use best professional judgment to determine the facility's annual average wastewater discharge flow (i.e., the permit writer should consider only the sources of "process wastewater discharge," as defined previously, when determining the annual average process wastewater discharge flow, allowing for up to 25 percent nonprocess wastewater). The annual average flow is defined as the average of daily flow measurements calculated over at least a year; however, if available, three to five years of data are preferable to obtain a representation of average daily flow.(2)

If no historical or actual process wastewater flow data exist, the permitting authority is advised to establish a reasonable estimate of the facility's projected flow representative of the entire term of the permit. This may include a request for the facility to measure process wastewater flows for a representative period of time to establish a flow basis. If a plant is planning significant changes in production during the effective period of the permit, the permitting authority may consider establishing multiple tiers of limitations as a function of these production changes. Alternatively, a permit may be modified during its term, either at the request of the permittee or another interested 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 could provide the basis for a permit modification (40 CFR 122.62(a)).

The permit writer should use the facility's annual average process wastewater discharge flow and no more than 25 percent additional flow contributed by existing nonprocess wastewater discharges to convert the end-of-pipe concentration-based limitations into mass-based limitations.

13.3.2 Point of Application

The BPT effluent limitations guidelines at Subcategory A, B, C, and/or D direct dischargers would be applicable to the final effluent at the point of discharge to waters of the United States and before dilution with significant amounts of nonprocess waters (i.e., end-of-pipe).

13.3.3 Monitoring and Compliance

The monitoring frequency for BPT effluent limitations guidelines for Subcategory A, B, C, and/or D direct dischargers should be determined by the permit authority.

Compliance with the end-of-pipe effluent limitations guidelines should be determined by multiplying the regulated pollutant concentration, measured in the effluent sample, by a conversion factor and by the total applicable wastewater flow discharged during the effluent sampling period, which is typically 24 hours. Thus, the mass compliance value should be based on the applicable flow discharged on the day of sampling, not on the long-term average flow rate used to establish the permit limitations and standards.

Table 13-1

BPT Effluent Limitations Guidelines for Direct Dischargers

Subcategory	Pollutant or Pollutant Property	BPT Effluent Limitation 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

(a) If these 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 percent multiplied by a variability factor of 2.2, then effluent limitations for COD corresponding to the lower concentration values must be applied.

REFERENCES

1. U.S. EPA, Office of Water. Statistical Support Document for the Effluent Limitations Guidelines for the Pharmaceutical Manufacturing Industry. EPA-821-B-98-007, U.S. Environmental Protection Agency, Washington, D.C., 1998.
2. U.S. EPA, Office of Water. Training Manual for NPDES Permit Writers. EPA 833-B-93-003, U.S. Environmental Protection Agency, Washington, D.C., 1993.
3. Osantowski, Richard and Richard Wullschleger. Evaluation of Activated Carbon for Enhanced COD Removal from Pharmaceutical Wastewater. Rexnord, Inc., Milwaukee, WI, 1987.