detail in Section IX.E.3 below, steam stripping technology and steam stripping with distillation technology are applied in-plant and minimize the dilution effects of commingling process wastewater streams and the transfer of volatile pollutants to air associated with other technologies. These technologies also allow the pharmaceutical manufacturing operation to recover the stripped solvents from the treatment process in an efficient and cost-effective manner from concentrated streams. These recovered solvents can then be recycled back into the process from which they were removed, reused in other manufacturing operations (e.g., in this industry or in other industries), or reused as "clean fuel" for boilers or other combustion devices. For further discussion of "clean fuels," see section XII.B of this preamble.

2. In-Plant Technologies Considered

EPA considered the following in-plant technologies to control solvent- and cyanide-laden wastewater generated by pharmaceutical manufacturing: (1) Steam stripping; (2) steam stripping with distillation; and (3) cyanide destruction. EPA concludes that steam stripping technology is the best technology available for removing high loadings and high concentrations of volatile organic pollutants from wastewater, and accordingly proposes BAT limitations for facilities with subcategory A and/or C operations on that technology basis. Fourteen plants reported using steam stripping technology and one facility reported using distillation technology for wastewater treatment in 1990. The demonstrated removal efficiencies for both technologies treating streams with high concentrations of highly strippable volatiles are greater than 99 percent. A detailed discussion of steam stripping and steam stripping with distillation (using fractional distillation columns with rectifying sections for difficult to strip volatile organic pollutants) and their use in the pharmaceutical manufacturing industry may be found in Section 7 of the TDD.

3. End-of-Pipe Technologies Considered

The end-of-pipe treatment technologies currently employed by the industry include: preliminary or primary treatment (neutralization, equalization, and primary clarification); biological or equivalent treatment (aerated stabilization basins with and without settling basins, oxidation ponds, and activated sludge systems); and physical/chemical treatment (multimedia filtration and chemically assisted clarification). In addition, EPA

has designated as advanced biological treatment a treatment configuration consisting of primary treatment plus some form of activated sludge treatment, which achieves better than 90 percent BOD₅ and 74 percent COD reduction from raw waste levels. EPA evaluated each of these available technologies in developing the limitations and standards proposed today. In addition to these technologies, the Agency also considered granular activated carbon (GAC) adsorption technology, which is an appropriate and available end-ofpipe treatment technology for pharmaceutical wastewater. All of the various technologies mentioned above are discussed in detail in Section 7 of the TDD.

All 35 direct dischargers responding to EPA's detailed questionnaire reported having some form of primary treatment in place in 1990. Thirty-one facilities reported having some form of biological or secondary treatment in place, either air- or oxygen-activated sludge treatment followed by secondary clarification and, in some cases, multimedia filtration and polishing ponds. One plant reported using GAC technology as end-of-pipe technology, and one plant reported using GAC technology in-plant.

E. Rationale for Selection of Technology Bases for Proposed Regulations

1. BPT

a. Introduction. EPA is today proposing revised BPT effluent limitations guidelines based on the Best Practicable Control Technology Currently Available (BPT) for BOD₅, TSS, and COD for subcategories A, B, C, and D of the pharmaceutical manufacturing industry. EPA is also proposing to revise existing BPT limitations for cyanide for facilities with subcategory A and/or C operations and to repeal the existing BPT cyanide limitations for facilities with B and/or D operations. The Clean Water Act explicitly authorizes EPA to revise all effluent limitations guidelines, including those based on best practicable technology, at least annually if appropriate. See CWA section 304(b). In the 1987 amendments to the Clean Water Act, Congress further required EPA to establish a schedule for the annual review and revision of promulgated effluent guidelines in accordance with section 304(b). See CWA section 304(m). Moreover, as discussed in Section V.A.4, above, EPA entered into a consent decree that requires EPA to propose and promulgate effluent guidelines for the pharmaceutical manufacturing industry,

as appropriate, including those authorized by section 304(b) for existing dischargers. See 304(m) Decree at 4–5. Because BPT guidelines are among those listed in section 304(b), EPA thus is required by the 304(m) Decree to propose and take final action on BPT guidelines for this industry, unless not appropriate.

EPA has determined that revising BPT limitations for the pharmaceutical manufacturing industry is indeed appropriate and important. The existing BPT guidelines for BOD₅, TSS, COD and cyanide for this industry, which were most recently revised in 1983, are based on secondary treatment data collected in the mid-1970s and cyanide destruction technology data collected in the early 1980s. Data from the 1990 detailed questionnaire indicate that there have been significant improvements in secondary treatment and cyanide destruction technologies in the industry since that time. Accordingly, the technology underpinnings of the current BPT limitations no longer reflect the "average of the best" technology currently available. Moreover, substantial environmental benefits would ensue from more stringent BPT limitations. For example, there would be significant reductions in the levels of COD and cyanide in addition to BOD₅ and TSS from current levels if BPT were revised. EPA has determined that revising the BPT limitations to reflect the best practicable control technology currently available is appropriate at this time.

b. Pollutants of concern. EPA is proposing to revise BPT effluent limitations controlling the discharge of BOD₅, TSS, COD, and, for facilities with subcategory A and/or C operations, cyanide (CN). EPA has determined that cyanide is not a pollutant of concern for facilities with subcategory B and/or D operations. Limitations for the pollutant parameter, pH, are not being revised.

c. Determination of technology basis of BPT. To determine the technology basis and performance level that constitutes BPT, EPA developed a database consisting of 1988 and 1989 effluent data supplied in response to the 1990 detailed questionnaire and its pretest form. The Agency determined that more than 29 of 35 direct dischargers and 23 indirect dischargers utilized biological treatment (activated sludge treatment). In addition, 10 direct and indirect discharging plants reported some form of cyanide destruction technology in place. Other technologies utilized include wastewater incineration (12 plants), effluent filtration (6 plants), and polishing ponds (8 plants).