process wastewater in such a way as to minimize the amount of wastewater that will require steam stripping with distillation, thereby reducing the adverse energy impacts that prevented EPA from selecting this technology as PSES.

EPA is proposing to set pretreatment standards for new sources based on PSNS Option 1 (steam stripping with distillation plus cyanide destruction) for priority and nonconventional pollutant for indirect discharging facilities with subcategory A and/or C operations. Similarly, EPA is proposing to set pretreatment standards for new sources based on PSNS Option 1 (steam striping with distillation) for facilities with subcategory B and/or D operations.

EPA considered the cost of the proposed PSNS technologies for new plants. EPA has concluded that such costs are not so great as to present a barrier to entry, as demonstrated by the fact that currently operating plants are using these technologies. The Agency also considered energy requirements and other non-water quality environmental impacts when comparing the three PSNS technology options for facilities with subcategroy A and/or C operations and the two PSNS technology options for facilities with subcategory B and/or D operations. EPA concluded that there would be only a slight difference in the energy requirements associated with Options 1, 2, and 3 for subcategory A and/or C facilities and with Options 1 and 2 for subcategory B and/or D facilities. There are no significant differences in the other non-water quality environmental impacts between the options considered.

7. BMP

EPA is not proposing any Best Management Practices (BMPs) today for the Pharmaceutical Manufacturing Category. However, EPA is soliciting comment on whether BMPs are applicable to the pharmaceutical manufacturing industry and, if so, what they should include. See Section XIV, solicitation number 31.0. See also the TDD at Appendix B for specific BMPs that EPA is considering adopting.

F. Determination of Long-Term Averages, Variability Factors, and Limitations

A detailed description of the statistical methodology used for the calculation of limitations is described in the Statistical Support Document. A summary of the methodology follows.

Limitations were based on actual concentrations of constituents measured in wastewaters treated by BAT

treatment systems when such data were available. Limitations were transferred based on engineering analysis when actual monitoring data were unavailable. For steam stripping and distillation technology, engineering analysis involved grouping constituents on the basis of their Henry's Law Constant. For biological treatment, the engineering analysis involved grouping constituents on the basis of their chemical structure and published data on relative biodegradability.

The calculation of the BAT daily limitations for constituents other than cyanide was performed by the following steps. The arithmetic long-term mean concentration was calculated for each facility dataset representing BAT treatment technology, and the median of the means was determined. A modified delta-lognormal distribution, the distribution model used by EPA in the Organic Chemicals, Plastics and Synthetic Fibers (OCPSF) and Pesticides Manufacturing rulemakings, was fit to daily concentration data from each facility dataset that had enough detected concentration values for parameter estimation. Variability factors were then computed for each of these datasets, and the average variability factor was determined. Finally, the daily maximum limitation was calculated by multiplying the median long-term mean by the average variability factor. The monthly average maximum limitation was calculated similarly except that the variability factor corresponding to the 95th percentile of the distribution of monthly averages was used instead of the 99th percentile of daily concentration measurements. The monthly average maximum limitation calculation assumes four measurements per month, or one per week.

The modified delta-lognormal distribution models the data as a mixture of non-detects and measured values. This distribution was selected because the data for most constituents consisted of a mixture of measured values and non-detects. The modified delta-lognormal distribution assumes that all non-detects have a value equal to the detection limit and the detected values follow a lognormal distribution.

A beta distribution rather than a deltalognormal was used to model cyanide data. The BAT treatment for cyanide requires the reprocessing of wastewater if effluent cyanide concentrations exceed 1 ppm. Therefore, the cyanide data from a properly operated treatment system should range between 0 and 1 ppm. Such data are appropriately modelled by the beta distribution. The parameters of the beta distribution were estimated from the cyanide dataset by the method of moments. Parameter estimates were then substituted in the beta distribution from which the daily limitation (99th percentile) was calculated. The monthly average cyanide (based on 4 daily measurements) limitation was estimated in a similar fashion.

The calculation of the proposed BPT limitations was based on measured concentrations of BOD5, COD, and TSS measured in wastewaters treated by BPT systems. A 1-day and 30-day limitation was determined for each BPT facility dataset from a modified delta-lognormal distribution that was fit to the data. These limitations were then averaged across the datasets to determine the overall 1-day and 30-day maximum limitations. An intermediate step involved adjusting the modeled variability to account for day-to-day correlation in concentrations of BOD₅, COD, and TSS. The adjustment was based on a lag-1 autocorrelation time series model estimated from adjacent day observations, the same approach adopted in the OCPSF rulemaking. For datasets having an insufficient number of adjacent day observations to estimate an autocorrelation an average value was assumed.

G. Costs

The Agency estimated the cost for the pharmaceutical manufacturing industry to achieve each of the effluent limitations and standards proposed today. These estimated costs are summarized in this section and discussed in more detail in section 10 of the Technical Development Document. All cost estimates are expressed in 1990 dollars (the year for which EPA received questionnaire responses and data submissions). The cost components reported in this section are engineering estimates of the capital cost of purchasing and installing equipment and the annual operating and maintenance costs associated with that equipment. The total annualized cost, which is used to estimate economic impacts, better describes the actual compliance cost that a company will incur because it allows for interest, depreciation, and taxes. A summary of the economic impact analysis for the proposed regulation is contained in Section XI.B of today's notice. See also the Economic Impact Analysis.

1. BPT

The Agency used a plant-specific engineering cost assessment to estimate the costs of achieving the proposed BPT limitations. If a plant's reported 1990 discharges of BOD_5 , TSS, COD and, in the case of facilities with subcategory A