

required. The Agency also solicits information, comments, and data on the following technical areas:

a. Data characterizing in-facility process wastewater streams bearing pollutants proposed to be regulated, including ammonia concentration in the wastewater stream, stream pH, stream TDS and TSS, and information on the ionic species in the stream.

b. Information on new steam strippers installed since 1990 for the treatment of pharmaceutical process wastewater.

c. Information on the storage capacity used by facilities prior to steam stripping.

d. Information on steam generation and cost, including how much steam is generated on-site and at what cost, how much steam is purchased from off-site sources and at what cost, steam condition, and steam pressure used by the facility.

e. Information on scaling in steam strippers including information concerning the issues, problems, and solutions to scaling.

f. Information on the operation and maintenance costs for running steam strippers at pharmaceutical manufacturing facilities.

3.0 Basis for Pollutant Loading Estimates

EPA requests information from plants that completed Table 3-2 of the "1990 Pharmaceutical Manufacturing Survey" but did not indicate a technical basis for their loadings estimates (*i.e.*, air emissions from wastewater, discharges to surface waters/sewers etc.). The Agency requests that facilities specify the method and underlying assumptions used in making air emission and water discharge estimates for individual pollutants, the loading estimate values either estimated or measured, and the uncertainty associated with the method used to estimate these quantities.

4.0 Subcategorization

EPA is proposing to maintain the existing subcategorization scheme. The rationale for maintaining this scheme is discussed in Section IX.A.3 of this preamble.

4.1 Comments on Maintaining the Existing Subcategorization Scheme

EPA solicits comments regarding the decision to maintain the existing scheme.

4.2 Alternative Regulatory Schemes

The Agency also solicits suggestions for alternative regulatory schemes.

5.0 Definition of Research Operations

5.1 Definition

Research operations are defined and discussed in section IX.A.4 of this preamble. EPA solicits comments regarding the definition of research operations for the pharmaceutical manufacturing category.

5.2 Research Operation Wastewater in Combination With Other Subcategory Wastewater

EPA solicits comment on whether wastewaters generated from bench-scale pharmaceutical research operations at facilities with other pharmaceutical subcategory wastewaters (A, B, C, D) should be subject to the proposed subcategory A, B, C, and/or D standards and limitations rather than the existing BPT limitations for subcategory E.

6.0 Characterization of Individual Process Wastewater Streams

The Agency anticipates that at most facilities, a greater mass of volatile organic pollutants will be concentrated in specific wastewater streams rather than being evenly distributed in all wastewater streams. Nonetheless, EPA has assumed for purposes of this proposal that wastewater streams with volatile organic pollutants at concentrations above the distillation treatability target concentrations would require steam stripping. Because of a lack of detailed and consistent flow and pollutant characterization data in the plant responses to the section 308 questionnaire, EPA assumed, when estimating costs associated with the steam stripping and steam stripping with distillation options, that facilities would be treating all or most of the process wastewater generated by their individual plants. EPA believes that this is not a realistic assumption and that the costs developed for in-plant steam stripping and steam stripping with distillation are substantially overstated. As a practical matter, EPA anticipates that plants will attempt to segregate and treat the most concentrated volatile pollutant-bearing wastewater streams from those not requiring treatment, thus reducing the amount of wastewater that will be treated. Since amount of flow entering a steam stripper or steam stripper with distillation unit is a significant cost component in the design of these units (*i.e.*, the greater the flow the greater the cost), reductions in input flows should result in significant cost reductions.

6.1 Data on Flow and Organic Pollutant Distribution

In order to obtain better estimates of the volume and pollutant characterization of wastewaters requiring treatment, EPA solicits data from plants in the industry on the distribution of volatile organic pollutants in process wastewater streams. These data should specify: (1) The number and measured or estimated volume of *individual* process wastewater streams; (2) the types of organics in these waste streams and the ranges of organic pollutant concentrations either measured or estimated in these streams (*e.g.*, <1 mg/l, 1-10 mg/l, 10-100 mg/l, 100-1,000 mg/l, >1,000 mg/l); and (3) the ten organic pollutants found or expected to be found in these streams in the highest concentrations. In any cases where these data are estimates, the underlying assumptions for these estimates will need to be specified. In cases where plants undertake to generate data from process wastewater flow measurements and pollutant analyses, the measurement and analytical methods used to generate these data also will need to be specified. The Agency strongly suggests that any such plants which choose to generate these data should contact EPA staff (please refer to the **FOR FURTHER INFORMATION** section of this preamble) for guidance on details of the scope and methods of data collection and supporting documentation.

6.2 Wastewater Stream Segregation

EPA anticipates that plants would segregate volatile bearing wastewater from non-volatile bearing wastewater. EPA solicits comments supported by data concerning whether stream segregation of volatile bearing streams from non-volatile bearing streams is feasible and/or practical.

7.0 BAT Limitations for Direct Discharging Facilities With Subcategory B and D Operations Based on Steam Stripping or Steam Stripping With Distillation

In section IX.E.3.c(2) of this preamble, EPA speculated that pollutant loading data from years other than 1990 may indicate that in-plant steam stripping technology or in-plant steam stripping with distillation technology is an appropriate basis for BAT regulations for facilities with subcategory B and/or D operations. Accordingly, EPA solicits volatile pollutant loading data from direct discharging facilities with subcategory B and D operations for