Title 40—Protection of the Environment

CHAPTER I—ENVIRONMENTAL PROTECTION AGENCY

SUBCHAPTER N—EFFUENT GUIDELINES AND STANDARDS

[FRL 644-1]

PART 439—PHARMACEUTICAL MANUFACTURING POINT SOURCE CATEGORY

Interim Final Rulemaking

Notice is hereby given that effluent limitations and guidelines for existing sources to be achieved by the application of best practicable control technology currently available as set forth in interim final form below are promulgated by the Environmental Protection Agency (EPA). The regulation set forth below establishes Part 439, Pharmaceutical Manufacturing Point Source Category, and will be applicable to existing sources for the fermentation products subcategory (Subpart A), the extraction products subcategory (Subpart B), the chemical synthesis products subcategory (Subpart C), the mixing/compounding and formulation subcategory (Subpart D), and the research subcategory (Subpart E) of the pharmaceutical manufacturing point source category pursuant to sections 301, and 304 (b) and (c), of the Federal Water Pollution Control Act, as amended (33 U.S.C. 1251, 1311 and 1314 (b) and (c), 86 Stat. 816 et seq.; Pub. L. 92-500) (the Act). In the near future, the Agency intends to publish in proposed form effluent limitations and guidelines for existing sources to be achieved by the application of best available technology economically achievable, and standards of performance and pretreatment standards for existing point sources and new point sources. A description and discussion of this legal authority is contained in Appendix A to this preamble.

The pharmaceutical manufacturing point source category was first studied to determine whether separate limitations are appropriate for different segments within the category. This analysis included a determination of whether differences in raw material used, product produced, manufacturing process employed, age, size, wastewater constituents and other factors require development of separate limitations for different segments of the point source category. The raw waste characteristics for this point source were then identified. The control and treatment technologies existing within the category were identified in terms of the quantity and the chemical, physical, and biological characteristics of pollutants, and the effluent level resulting from the application of each of the technologies. This information was then evaluated in order to determine what levels of technology constitute the "best practicable control technology currently available." The data upon which the above analysis was performed included EPA permit applications, EPA sampling and inspections, consultant reports, and industry submissions. A summary of the method of study, the several factors considered in subcategorization and the conclusions reached are set forth as Appendix B to this preamble.

Although the percent removal approach used in this regulation represents a departure from the conventional production based limitations, it is the only feasible alternative using the present data base. This approach should not be construed as setting a precedent for future industrial limitations. There may be modification of the format utilized in this rulemaking when further analysis is conducted of expected new data. While the regulation published in interim final form today does not present a specific numerical limitation, the effect of today's publication is the same as if numbers for BOD5 and COD were presented. The permit writer may arrive at effluent limits for BOD5 and COD by applying to the raw waste load for each plant a percent reduction known to be attainable, and a variability factor. This approach does not disallow or mandate in-house pollution control practices; it merely assures that the total pollution loading from all facilities are reduced on an equitable basis. This regulation does not prohibit introduction of mycelia from fermentation processes in subcategory A into wastewater treatment systems, but the Agency is restudying this practice.

Although the TSS maximum for the average of daily TSS values for any calendar month is not specified for subcategories A and C in this regulation, it is not the intent of the Agency to remain mute on this parameter. Additional TSS data on these two subcategories will be compiled as expeditiously as possible in order to amend the regulations for subcategories in regard to TSS. For subcategories B, D and E the average of daily TSS values for any calendar month shall not exceed 52 mg/l.

Although daily maximum numbers for BOD5, COD and TSS are omitted in this regulation, it is anticipated that the permit writer will review each facility on a case by case basis and supply appropriate daily maximum limitations under authority of section 402 of the FWPCAA, and in compliance with regulations published in 40 CFR Parts 124 and 125. In the same manner, those known pollutants at a site specific location but not identified in this regulation may be assigned appropriate effluent limitation values by the permit writer.

The report entitled "Development Document for Interim Final Effluent Limitations, Guidelines and Proposed New Source Performance Standards for the Pharmaceutical Manufacturing Point Source Category" details the analysis undertaken in support of the interim final regulation set forth herein and is available for inspection at the EPA Public Information Reference Unit, Room 2922 (EPA Library), Waterside Mall, 401 M St., S.W., Washington, D.C. 20460, at all EPA regional offices and at State water pollution control offices. A supplementary analysis prepared for EPA of the possible economic effects of the regulation is also available for inspection at these locations. Copies of both of these documents are being sent to persons or institutions affected by the proposed regulation or who have placed themselves on a mailing list for this purpose (see EPA's Advance Notice of Public Review Procedures, 38 F.R. 21202, August 6, 1973). An additional limited number of copies of both reports are available. Persons wishing to obtain a copy may write the Environmental Protection Agency, Effluent Guidelines Division, Washington, D.C. 20460, Attention: Distribution Officer, WH-552.

When this regulation is promulgated in final rather than interim form, revised copies of the Development Document will be available from the Superintendent of Documents, Government Printing Office, Washington, D.C. 20402. Copies of the economic analysis document will be available through the National Technical Information Service, Springfield, VA 22151.

Prior to this publication, many agencies and groups were consulted and given the opportunity to participate in the development of these limitations, guidelines and standards. All participating agencies have been informed of project developments. An initial draft of the Development Document was sent to all participants and comments were solicited on that report. A summary of these comments and the Agency's response and consideration of these is contained in Appendix C to this preamble.

The Agency today promulgates regulations which are explicitly addressed to the control of BOD5, COD and pH. TSS is controlled for subcategories B, D and E.

The oxygen demanding properties of these wastes result from the presence of both organic and inorganic compounds in the wastewaters. The release of oxygen demanding substances will be reduced when the discharger employs recommended technology. To meet the 1977 levels, a discharger can either rely on in-plant treatment or an end of the pipe treatment. Another option available would be to use a combination of both.

The Agency has studied the economic and inflationary impact of the costs of these regulations and has made the following conclusions. It was found that only a few plants may have significant difficulty in implementing a treatment technology based on biological treatment. None of the 58 plants that are affected by the 1977 regulations are expected to close or curtail production. This analysis meets all of the requirements of economic and inflationary impact statements and is hereby certified by the Administrator in accordance with Executive Order No. 11821.

The Agency is subject to an order of the United States District Court for the District of Columbia entered in "Natural Resources Defense Council v Train" et. al. (Civ. No. 1609-73) which requires the promulgation of regulations for this industry category no later than September 1, 1976. This order also requires that such regulations become effective immediately

upon publication. In addition, it is necessary to promulgate regulations establishing limitations on the discharge of pollutants from point sources in this category so that the process of issuing permits to individual dischargers under section 402 of this Act is not delayed.

It has not been practicable to develop and publish regulations for this category in proposed form, to provide a 30 day comment period, and to make any necessary revisions in light of the comments received within the time constraints imposed by the court order referred to above. Accordingly, the Agency has determined pursuant to 5 U.S.C. 553(b) that notice and comment on the interim final regulations would be impracticable and contrary to the public interest. Good cause is also found for these regulations to become effective immediately upon publication.

Interested persons are encouraged to submit written comments. Comments should be submitted in triplicate to the Environmental Protection Agency, 401 M St., SW., Washington, D.C. 20460, Attention: Distribution Officer, WH-552. Comments on all aspects of the regulation are solicited. The Agency especially solicits comments and/or data on cost of waste treatment, including processing of mycelia, solvents, and broths. In the event comments are in the nature of criticisms as to the adequacy of data which are available, or which may be relied upon by the Agency, comments should identify and, if possible, provide any additional data which may be available and should indicate why such data suggest amendment or modification of the regulation. In the event comments address the approach taken by the Agency in establishing an effluent limitation or guideline, EPA solicits suggestions as to what alternative approach should be taken and why and how this alternative better satisfies the detailed requirements of sections 301 and 304(b) of the Act.

A copy of all public comments will be available for inspection and copying at the EPA Public Information Reference Unit, Room 2922 (EPA Library), Waterside Mall, 401 M Street, SW., Washington, D.C. 20460. A copy of preliminary draft contractor reports, the Development Document and economic study referred to above, and certain supplementary materials supporting the study of the industry concerned will also be maintained at this location for public review and copying. The EPA information regulation, 40 CFR Part 2, provides that a reasonable fee may be charged for copying.

All comments received on or before January 17, 1977, and the availability of the Development Document supporting this interim final regulation will be considered. Steps previously taken by the Environmental Protection Agency to facilitate public response within this time period are outlined in the advance notice concerning public review procedures published on August 6, 1973 (38 FR 21202). In the event that the final regulation differs substantially from the interim final regulation set forth herein the Agency will consider modification of any permits issued in accordance with this interim final regulation.

Section 8 of the FWPCA authorizes the Small Business Administration, through its economic disaster loan program, to make loans to assist any small business concern in effecting additions to or alterations in their equipment, facilities, or methods of operation so as to meet water pollution control requirements under the FWPCA, if the concern is likely to suffer a substantial economic injury without such assistance.

For further details on this Federal loan program write to EPA, Office of Analysis and Evaluation, WH-586, 401 M St., SW., Washington, D.C. 20460.

In consideration of the foregoing, 40 CFR Part 439 is hereby established as set forth below.

Dated: November 9, 1976.

JOHN QUARLES,
Acting Administrator.

Subpart A—Fermentation Products Subcategory

Sec.

AUTHORITY: Secs. 301, 304 (b) and (c) and 306(b), Federal Water Pollution Control Act, as amended (33 U.S.C. 1251, 1311, 1314 (b) and (c) and 1316(b), 86 Stat. 816 et seq.; Pub. L. 92-500) (the Act).

Subpart A—Fermentation Products Subcategory

§ 439.10 Applicability; description of the fermentation products subcategory.

The provisions of this subpart are applicable to discharges resulting from the manufacture of pharmaceuticals by fermentation.

§ 439.11 Specialized definitions.

For the purpose of this subpart:

(a) Except as provided below, the general definitions, abbreviations and methods of analysis set forth in Part 401 of this chapter shall apply to this subpart.

(b) The term "product" shall mean pharmaceutical products derived from fermentation processes.

§ 439.12 Effluent limitations and guidelines representing the degree of effluent reduction attainable by the application of the best practicable control technology currently available.

In establishing the limitations set forth in this section, EPA took into account all information it was able to collect, develop and solicit with respect to factors (such as age and size of plant, raw materials, manufacturing processes, products produced, treatment technology available, energy requirements and costs, which can affect the industry subcategorization and effluent levels established. It is, however, possible that data which would affect these limitations have not been available and, as a result, these limitations should be adjusted for certain plants in this industry. An individual discharger or other interested persons may submit evidence to the Regional Administrator (or to the State, if the State has the authority to issue NPDES permits) that factors relating to the equipment or facilities involved, the process applied, or other such factors related to such discharger are fundamentally different from the factors considered in the establishment of the guidelines. On the basis of such evidence or other available information, the Regional Administrator (or the State) will make a written finding that such factors are or are not fundamentally different for that facility compared to those specified in the Development Document. If such fundamentally different factors are found to exist, the Regional Administrator or the State shall establish for the discharger effluent limitations in the NPDES permit either more or less stringent than the limitations established herein, to the extent dictated by such fundamentally different factors. Such limitations must be approved by the Administrator of the Environmental Protection Agency. The Administrator may approve or disapprove such limitations, specify other limitations, or initiate proceedings to revise these regulations.

(a) The following limitations establish the quantity or quality of pollutants or pollutant properties, controlled by this

paragraph, which may be discharged by a fermentation products plant from a point source subject to the provisions of this paragraph after application of the best practicable control technology currently available:

(1) The allowable effluent discharge limitation for the daily average mass of BOD5 in any calendar month shall be expressed in mass per unit time and shall specifically reflect not less than 90 percent reduction in the long term daily average raw waste content of BOD5 multiplied by a variability Factor of 3.0.

(2) The allowable effluent discharge limitation for the daily average mass of COD in any calendar month shall be expressed in mass per unit time and shall specifically reflect not less than 74 percent reduction in the long term daily average raw waste content of COD multiplied by a variability factor of 2.2.

(3) The long term daily average raw waste load for the pollutant BOD5 and COD is defined as the average daily mass of each pollutant influent to the wastewater treatment system over a 12 consecutive month period within the most recent 36 months, which shall include the greatest production effort.

(4) To assure equity in regulating discharges from the point sources covered by this subpart of the point source category, calculation of raw waste loads of BOD5 and COD for the purpose of determining NPDES permit limitations (i.e., the base numbers to which the percent reductions are applied) shall exclude any waste load associated with mycelia, spent beers (broths) and solvents in those raw waste loads: *Provided,* That residual amounts of mycelia, spent beers and solvents remaining after the practice of recovery and/or separate disposal or reuse may be included in calculation of raw waste loads. These practices of removal, disposal or reuse include physical separation and removal of mycelia, recovery of solvents from waste streams, incineration of concentrated solvent waste streams (including tar still bottoms) and broth concentrated for disposal other than to the treatment system. This regulation does not prohibit inclusion of such wastes in the raw waste loads in fact, nor does it mandate any specific practice, but rather describes the rationale for determining the permit conditions. These limits may be achieved by any one of several or a combination thereof of programs and practices.

(5) The pH shall be within the range of 6.0–9.0 standard units.

Subpart B—Extraction Products Subcategory

§ 439.20 Applicability; description of the extraction products subcategory.

The provisions of this subpart are applicable to discharges resulting from the manufacture of pharmaceuticals by extraction.

§ 439.21 Specialized definitions.

For the purpose of this subpart:

(a) Except as provided below, the general definitions, abbreviations and methods of analysis set forth in Part 401 of this chapter shall apply to this subpart.

(b) The term "product" shall mean biological and natural extraction products. This subcategory shall include blood fractions, vaccines, serums, animal bile derivatives, endocrine products and isolation of medicinal products, such as alkaloids, from botanical drugs and herbs.

§ 439.22 Effluent limitations and guidelines representing the degree of effluent reduction attainable by the application of the best practicable control technology currently available.

In establishing the limitations set forth in this section, EPA took into account all information it was able to collect, develop and solicit with respect to factors (such as age and size of plant, raw materials, manufacturing processes, products produced, treatment technology available, energy requirements and costs) which can affect the industry subcategorization and effluent levels established. It is, however, possible that data which would affect these limitations have not been available and, as a result, these limitations should be adjusted for certain plants in this industry. An individual discharger or other interested persons may submit evidence to the Regional Administrator (or to the State, if the State has the authority to issue NPDES permits) that factors relating to the equipment or facilities involved, the process applied, or other such factors related to such discharger are fundamentally different from the factors considered in the establishment of the guidelines. On the basis of such evidence or other available information, the Regional Administrator (or the State) will make a written finding that such factors are or are not fundamentally different for that facility compared to those specified in the Development Document. If such fundamentally different factors are found to exist, the Regional Administrator or the State shall establish for the discharger effluent limitations in the NPDES permit either more or less stringent than the limitations established herein, to the extent dictated by such fundamentally different factors. Such limitations must be approved by the Administrator of the Environmental Protection Agency. The Administrator may approve or disapprove such limitations, specify other limitations, or initiate proceedings to revise these regulations.

(a) The following limitations establish the quantity or quality of pollutants or pollutant properties, controlled by this paragraph, which may be discharged by an extraction products plant from a point source subject to the provisions of this paragraph after application of the best practicable control technology currently available:

(1) The allowable discharge for the pollutant parameters BOD5 and COD shall be expressed in mass per unit time and shall represent the specified wastewater treatment efficiency in terms of a residual discharge associated with an influent to the wastewater treatment plant corresponding to the maximum production for a given pharmaceutical plant.

(2) The allowable effluent discharge limitation for the daily average mass of BOD5 *n any calendar month shall specifically* reflect not less than 90 percent reduction in the long term daily average raw waste content of BOD5 multiplied by a variability factor of 3.0.

(3) The allowable effluent discharge limitation for the daily average mass of COD in any calendar month shall specifically reflect not less than 74 percent reduction in the long term daily average raw waste content of COD multiplied by a variability factor of 2.2.

(4) The long term daily average raw waste load for the pollutant BOD5 and COD is defined as the average daily mass of each pollutant influent to the wastewater treatment system over a 12 consecutive month period within the most recent 36 months, which shall include the greatest production effort.

(5) To assure equity in regulating discharges from the point sources covered by this subpart of the point source category, calculation of raw waste loads of BOD5 and COD for the purpose of determining NPDES permit limitations (i.e., the base numbers to which the percent reductions are applied) shall exclude any waste load associated with solvents in those raw waste loads; *Provided,* That residual amounts of solvents remaining after the practice of recovery and/or separate disposal or reuse may be included in calculation of raw waste loads. These practices of removal, disposal or reuse include recovery of solvents from waste streams and incineration of concentrated solvent waste streams (including tar still bottoms). This regulation does not prohibit inclusion of such wastes in the raw waste loads in fact, nor does it mandate any specific practice, but rather describes the rationale for determining the permit conditions. These limits may be achieved by any one of several or a combination thereof of programs and practices.

(6) The average of daily TSS values for any calendar month shall not exceed 52 mg/l.

(7) The pH shall be within the range of 6.0–9.0 standard units.

Subpart C—Chemical Synthesis Products Subcategory

§ 439.30 Applicability; description of the chemical synthesis plants subcategory.

The provisions of this subpart are applicable to discharges resulting from the manufacture of pharmaceuticals by chemical synthesis.

§ 439.31 Specialized definitions.

For the purpose of this subpart:

(a) Except as provided below, the general definitions, abbreviations and methods of analysis set forth in Part 401 of this chapter shall apply to this subpart.

(b) The term "product" shall mean chemical synthesis products.

§ 439.32 Effluent limitations and guidelines representing the degree of effluent reduction attainable by the application of the best practicable control technology currently available.

In establishing the limitations set forth in this section, EPA took into account all information it was able to collect, develop and solicit with respect to factors (such as age and size of plant, raw materials, manufacturing processes, products produced, treatment technology available, energy requirements and costs) which can affect the industry subcategorization and effluent levels established. It is, however, possible that data which would affect these limitations have not been available and, as a result, these limitations should be adjusted for certain plants in this industry. An individual discharger or other interested person may submit evidence to the Regional Administrator (or to the State, if the State has the authority to issue NPDES permits) that factors relating to the equipment or facilities involved, the process applied, or other such factors related to such discharger are fundamentally different from the factors considered in the establishment of the guidelines. On the basis of such evidence or other available information, the Regional Administrator (or the State) will make a written finding that such factors are or are not fundamentally different for that facility compared to those specified in the Development Document. If such fundamentally different factors are found to exist, the Regional Administrator or the State shall establish for the discharger effluent limitations in the NPDES permit either more or less stringent than the limitations established herein, to the extent dictated by such fundamentally different factors. Such limitations must be approved by the Administrator of the Environmental Protection Agency. The Administrator may approve or disapprove such limitations, specify other limitations, or initiate proceedings to revise these regulations.

(a) The following limitations establish the quantity or quality of pollutants or pollutant properties, controlled by this paragraph, which may be discharged by chemical synthesis plants from a point source subject to the provisions of this paragraph after application of the best practicable control technology currently available:

(1) The allowable discharge for the pollutant parameters BOD5 and COD shall be expressed in mass per unit time and shall represent the specified wastewater treatment efficiency in terms of a residual discharge associated with an influent to the wastewaster treatment plant corresponding to the maximum production for a given pharmaceutical plant.

(2) The allowable effluent discharge limitation for the daily average mass of BOD5 in any calendar month shall specifically reflect not less than 90 percent reduction in the long term daily average raw waste content of BOD5 multiplied by a variability factor of 3.0.

(3) The allowable effluent discharge limitation for the daily average mass of COD in any calendar month shall specifically reflect not less than 74 percent reduction in the long term daily average raw waste content of COD multiplied by a variability factor of 2.2.

(4) The long term daily average raw waste load for the pollution BOD5 and COD is defined as the average daily mass of each pollutant influent to the wastewater treatment system over a 12 consecutive month period within the most recent 36 months, which shall include the greatest production effort.

(5) To assure equity in regulating discharges from the point sources covered by this subpart of the point source category, calculation of raw waste loads of BOD5 and COD for the purpose of determining NPDES permit limitations (i.e., the base numbers to which the percent reductions are applied) shall exclude any waste load associated with solvents in those raw waste loads: *Provided*, That residual amounts of solvents remaining after the practice of recovery and/or separate disposal or reuse may be included in calculation of raw waste loads. These practices of removal, disposal or reuse include recovery of solvents from waste streams and incineration of concentrated solvent waste streams (including tar still bottoms). This regulation does not prohibit inclusion of such wastes in the raw waste loads in fact, nor does it mandate any specific practice, but rather describes the rationale for determining the permit conditions. These limits may be achieved by any one of several or a combination thereof of programs and practices.

(6) The pH shall be within the range of 6.0 to 9.0 standard units.

Subpart D—Mixing/Compounding and Formulation Subcategory

§ 439.40 Applicability; description of the mixing/compounding and formulation subcategory.

The provisions of this subpart are applicable to discharges resulting from mixing/compounding and formulation operations of pharmaceutical products.

§ 439.41 Specialized definitions.

For the purpose of this subpart:

(a) Except as provided below, the general definitions, abbreviations and methods of analysis set forth in Part 401 of this chapter shall apply to this subpart.

(b) The term "product" shall mean products from plants which blend, mix, compound, and formulate pharmaceutical ingredients. Pharmaceutical preparations for human and veterinary use such as ampuls, tablets, capsules, vials, ointments, medicinal powders, solutions and suspensions are included.

§ 439.42 Effluent limitations and guidelines representing the degree of effluent reduction attainable by the application of the best practicable control technology currently available.

In establishing the limitations set forth in this section, EPA took into account all information it was able to collect, develop and solicit with respect to factors (such as age and size of plant, raw materials, manufacturing processes, products produced, treatment technology available, energy requirements and costs) which can affect the industry subcategorization and effluent levels established. It is, however, possible that data which would affect these limitations have not been available and, as a result, these limitations should be adjusted for certain plants in this industry. An individual discharger or other interested person may submit evidence to the Regional Administrator (or to the State, if the State has the authority to issue NPDES permits) that factors relating to the equipment or facilities involved, the process applied, or other such factors related to such discharger are fundamentally different from the factors considered in the establishment of the guidelines. On the basis of such evidence or other available information, the Regional Administrator (or the State) will make a written finding that such factors are or are not fundamentally different for that facility compared to those specified in the Development Document. If such fundamentally different factors are found to exist, the Regional Administrator or the State shall establish for the discharger effluent limitations in the NPDES permit either more or less stringent than the limitations established herein, to the extent dictated by such fundamentally different factors. Such limitations must be approved by the Administrator of the Environmental Protection Agency. The Administrator may approve or disapprove such limitations, specify other limitations, or initiate proceedings to revise these regulations.

(a) The following limitations establish the quantity or quality of pollutants or pollutant properties, controlled by this paragraph, which may be discharged by a mixing/compounding and formulation plant from a point source subject to the provisions of this paragraph after application of the best practicable control technology currently available:

(1) The allowable discharge for the pollutant parameters BOD5 and COD shall be expressed in mass per unit time and shall represent the specified wastewater treatment efficiency in terms of a residual discharge associated with an influent to the wastewater treatment plant corresponding to the maximum production for a given pharmaceutical plant.

(2) The allowable effluent discharge limitation for the daily average mass of BOD5 in any calendar month shall specifically reflect not less than 90 percent reduction in the long term daily average raw waste content of BOD5 multiplied by a variability factor of 3.0.

(3) The allowable effluent discharge limitation for the daily average mass of COD in any calendar month shall specifically reflect not less than 74 percent reduction in the long term daily average raw waste content of COD multiplied by a variability factor of 2.2.

(4) The long term daily average raw waste load for the pollutant BOD5 and COD is defined as the average daily mass of each pollutant influent to the wastewater treatment system over a 12 consecutive month period within the most recent 36 months, which shall include the greatest production effort.

(5) To assure equity in regulating discharges from the point sources covered by this subpart of the point source category, calculation of raw waste loads of BOD5 and COD for the purpose of determining NPDES permit limitations (i.e., the base numbers to which the percent reductions are applied) shall exclude any waste load associated with solvents in those raw waste loads; *Provided*, That residual amounts of solvents remaining after the practice of recovery and/or separate disposal or reuse may be included in calculation of raw waste loads. These practices of removal, disposal or reuse include recovery of solvents from waste streams and incineration of concentrated solvent waste streams (including tar still bottoms). This regulation does not prohibit inclusion of such wastes in the raw waste loads in fact, nor does it mandate any specific practice, but rather describes the rationale for determining the permit conditions. These limits may be achieved by any one of several or a combination thereof of programs and practices.

(6) The average of daily TSS values for any calendar month shall not exceed 52 mg/l.

(7) The pH shall be within the range of 6.0 to 9.0 standard units.

Subpart E—Research Subcategory

§ 439.50 **Applicability; description of the research subcategory.**

The provisions of this subpart are applicable to discharges resulting from pharmaceutical research.

§ 439.51 **Specialized definitions.**

For the purpose of this subpart:

(a) Except as provided below, the general definitions, abbreviations and methods of analysis set forth in Part 401 of this chapter shall apply to this subpart.

(b) The term "product" shall mean products or service resulting from pharmaceutical research, which includes microbiological, biological and chemical operations.

§ 439.52 **Effluent limitations and guidelines representing the degree of effluent reduction attainable by the application of the best practicable control technology currently available.**

In establishing the limitations set forth in this section, EPA took into account all information it was able to collect, develop and solicit with respect to factors (such as age and size of plant, raw materials, manufacturing processes, products produced, treatment technology available, energy requirements and costs) which can affect the industry subcategorization and effluent levels established. It is, however, possible that data which would affect these limitations have not been available and, as a result, these limitations should be adjusted for certain plants in this industry. An individual discharger or other interested persons may submit evidence to the Regional Administrator (or to the State, if the State has the authority to issue NPDES permits) that factors relating to the equipment or facilities involved, the process applied, or other such factors related to such discharger are fundamentally different from the factors considered in the establishment of the guidelines. On the basis of such evidence or other available information, the Regional Administrator (or the State) will make a written finding that such factors are or are not fundamentally different for that facility compared to those specified in the Development Document. If such fundamentally different factors are found to exist, the Regional Administrator or the State shall establish for the discharger effluent limitations in the NPDES permit either more or less stringent than the limitations established herein, to the extent dictated by such fundamentally different factors. Such limitations must be approved by the Administrator of the Environmental Protection Agency. The Administrator may approve or disapprove such limitations, specify other limitations, or initiate proceedings to revise these regulations.

(a) The following limitations establish the quantity or quality of pollutants or pollutant properties, controlled by this paragraph, which may be discharged by a pharmaceutical research operation from a point source subject to the provisions of this paragraph after application of the best practicable control technology currently available:

(1) The allowable discharge for the pollutant parameters BOD5, and COD shall be expressed in mass per unit time and shall represent the specified wastewater treatment efficiency in terms of a residual discharge associated with an influent to the wastewater treatment plant coresponding to the maximum research effort for a given pharmaceutical plant.

(2) The allowable effluent discharge limitation for the daily average mass of BOD5 in any calendar month shall specifically reflect not less than 90 percent reduction in the long term daily average raw waste content of BOD5 multiplied by a variability factor of 3.0.

(3) The allowable effluent discharge limitation for the daily average mass of COD in any calendar month shall specifically reflect not less than 74 percent reduction in the long term daily average raw waste content of COD multiplied by a variability factor of 2.2.

(4) The long term daily average raw waste load for the pollutant BOD5 and COD is defined as the average daily mass of each pollutant influent to the wastewater treatment system over a 12 consecutive month period within the most recent 36 months.

(5) To assure equity in regulating discharges from the point sources covered by this subpart of the point source category, calculation of raw waste loads of BOD5 and COD for the purpose of determining NPDES permit limitations (i.e., the base numbers to which the percent reductions are applied) shall exclude any waste load associated with solvents in those raw waste loads; *Provided*, That residual amounts of solvents remaining after the practice of recovery and/or separate disposal or reuse may be included in calculation of raw waste loads. These practices of removal, disposal or reuse include recovery of solvents from waste streams and incineration of concentrated solvent waste streams (including tar still bottoms). This regulation does not prohibit inclusion of such wastes in the raw waste loads in fact, nor does it mandate any specific practice, but rather describes the rationale for determining the permit conditions. These limits may be achieved by any one of several or a combination thereof programs and practices.

(6) The average of daily TSS values for any calendar month shall not exceed 52 mg/l.

(7) The pH shall be within the range of 6.0 to 9.0 standard units.

Appendix A—Legal Authority

Existing Point Sources

Section 301(b) of the Act requires the achievement by not later than July 1, 1977, of effluent limitations for point sources, other than publicly owned treatment works, which require the application of the best practicable control technology currently available as defined by the Administrator pursuant to section 304(b) of the Act. Section 301(b) also requires the achievement by not later than July 1, 1983, of effluent limitations for point sources, other than publicly owned treatment works, which require the application of best available technology economically achievable which will result in reasonable further progress toward the national goal of eliminating the discharge of all pollutants, as determined in accordance with regulations issued by the Administrator pursuant to section 304(b) of the Act.

Section 304(b) of the Act requires the Administrator to publish regulations providing guidelines for effluent limitations setting forth the degree of effluent reduction attainable through the application of the best practicable control technology currently available and the degree of effluent reduction attainable through the application of the best control measures and practices achievable including treatment techniques, process and procedural innovations, operating methods and other alternatives. The regulation herein sets forth effluent limitations and guidelines, pursuant to sections 301 and 304(b) of the Act, for the fermentation products subcategory (Subpart A), the extraction products subcategory (Subpart B), the chemical synthesis products subcategory (Subpart C), the mixing/compounding and formulation subcategory (Subpart D), and the research subcategory (Subpart E) of the pharmaceutical manufacturing point source category.

Section 304(c) of the Act requires the Administrator to issue to the States and appropriate water pollution control agencies information on the processes, procedures or operating methods which result in the elimination or reduction of the discharge of pollutants to implement standards of performance under section 306 of the Act. The report

entitled "Development Document for Interim Final Effluent Limitations, Guidelines and New Source Performance Standards for the Pharmaceutical Manufacturing Point Source Category" provides, pursuant to section 304(c) of the Act, information on such processes, procedures or operating methods.

APPENDIX B—TECHNICAL SUMMARY AND BASIS FOR REGULATIONS

This Appendix summarizes the basis of interim final effluent limitations and guidelines for existing sources.

(1) GENERAL METHODOLOGY

The effluent limitations and guidelines set forth herein were developed in the following manner. The point source category was first studied for the purpose of determining whether separate limitations are appropriate for different segments within the category. This analysis included a determination of whether differences in raw materials, products, manufacturing process employed, age, size, wastewater constituents and other factors require development of separate limitations for different segments of the point source category. The raw waste characteristics for each such segment were then identified. This included an analysis of the source, flow and volume of water used in the process employed, the sources of waste and wastewaters in the operation and the constituents of all wastewaters. The constituents of the wastewaters which should be subject to effluent limitations were identified.

The existing control and treatment technologies within each segment were examined. This included an identification of each distinct control and treatment technology, including both in-plant and end-of-process technologies, which exists or is capable of being designed for each segment. It also included an identification of, in terms of the amount of constituents and the chemical, physical, and biological characteristics of pollutants, the effluent level resulting from the application of each of the technologies. Problems with each treatment and control technology were also identified. In addition, the nonwater quality environmental impact, such as the effects of the application of these technologies upon other pollution problems, including air, solid waste, noise and radiation were examined. The energy requirements of each control and treatment technology were determined as well as the cost of the application of such technologies.

The information outlined above was then evaluated in order to determine what levels of technology constitute the "best practicable control technology currently available." In identifying such technologies, various factors were considered. These included the total cost of application of technology, the age of equipment and facilities involved, the process employed, the engineering aspects of the application of various types of control techniques, process changes, nonwater quality environmental impact (including energy requirements), potential benefits to be achieved by reducing pollution from this point source category and other factors.

The data upon which the above analysis was performed included EPA permit applications, EPA sampling and inspections, consultant reports, and industry submissions.

(2) Summary of conclusions with respect to the fermentation products subcategory (Subpart A), the extraction products subcategory (Subpart B), the chemical synthesis products subcategory (Subpart C), the mixing/compounding and formulation subcategory (Subpart D), and the research subcategory (Subpart E) of the pharmaceutical manufacturing point source category.

(i) *Subcategorization.* For the purpose of establishing effluent limitations and guidelines, the pharmaceutical industry was divided into subcategories. Factors such as type of product, raw waste loads, water requirements, type of manufacturing process, treatability of wastewaters, and other means were used to establish effluent limitations and guidelines for each of the specific subcategories. In general, the largest distinguishing factors are product yield, processing and treatability based on production volume and specific water requirements. This broad base subcategorization scheme simplifies the application of effluent limitations and guidelines for a complex mix of pharmaceutical production activity. For example, an inherent waste to the fermentation products manufacturing operations (Subcategory A) is the generation of considerable amounts of mycelia. This waste is not found in the manufacturing operations of the other four subcategories.

(ii) *Waste characteristics.* The known significant wastewater pollutants and pollutant properties resulting from the pharmaceutical industry include pH, total suspended solids, BOD5, COD, TOC, metals, organic solvents, and waste medicinal chemicals. BOD5, COD, and TOC, which are primary measurements for organic pollution, are evident in wastewaters from the pharmaceutical manufacturing point source category.

(iii) *Origin of wastewater pollutants.* Sources of wastewater pollutants in the pharmaceutical industry include aqueous wastes from fermenters, reactors, filtration systems, decanting systems, solvent extraction units, ion exchange regeneration, distillation vacuum exhaust scrubbers, caustic scrubbers, destruction of waste or returned products, process equipment cleanouts, production area washdowns, refining area washdowns, formulation equipment cleanup, and spill washdowns. Unlike many other point source categories, the regulations could not be established on a unit of production basis due to the non-continuous nature of processes, the different process routes to produce the same or similar products, the variety of refining options for a given product or class of products, the differing conversion efficiencies of raw materials to final products, the low absolute yields of some active ingredients, and the physical form of final products. Therefore, the removal efficiencies of the applicable and practical technology were applied. In this particular regulation, the degree of effluent reduction for BOD5 and COD shall have the same meaning as percent removal or percent removal efficiency.

In determining efficiencies to be used, the historical data from existing plants in the point source category were evaluated to discover the best operating wastewater treatment plants. The average efficiencies of the best treatment plants within a subcategory were established as the removal technology that should be applied to these subcategories. The average values from an array of eleven plants identified as the best wastewater treatment plants for all subcategories were as follows:

	Percent
BOD5 removal	94
COD removal	74
Effluent TSS	[1]274

[1] Mg/l for subcategories A and C, 17.3 mg/l for subcategories B, D and E.

The eleven exemplary plants were identified from the following profile of biological treatment systems. Only those plants that had high treatment efficiencies and for which representative historical data were available (identified by asterisks) were used in developing the effluent limitations. Furthermore, this BOD5 reduction (percent removal) may be accomplished by any number of treatment steps or any kind of wastewater treatment technology (physical, chemical, biological or any combination of these).

However, the Agency decided to lower the BOD5 percent removal from 94 to 90 in this interim final regulation in order to lessen the potential economic impact in the form of capital investment in subcategories A and C. The decision to extend the 90 percent reduction to all subcategories was based on the industry characteristic of complex manufacturing facilities covered by more than one subcategory and treatment of combined wastes in which that attributable to a specific process could not readily be identified.

In order to arrive at the 52 mg/l maximum value for the average of daily TSS values for any calendar month for subcategories B, D and E, exemplary plants number 14, 24 and 23 were averaged and a variability factor of 3.0 was applied. This variability factor represents the 99 percent probability to long term average ratio.

For subcategories A and C, the maximum value for the average of daily TSS values for any calendar month has not been presented at this time. Several plants that are used as exemplary plants for BOD5 and COD removal efficiencies do not qualify as exemplary plants for the purpose of determining final TSS concentrations for subcategories A and C. For example, Plant 02 cannot be considered an exemplary plant for the TSS calculation. This plant may or may not be lacking in secondary settling and NEIC has reported that this plant has had difficulty meeting its TSS permit limits in the past.

BIOLOGICAL TREATMENT PLANT PERFORMANCE DATA

Plant No.	Subcategory	BOD5 removal (percent)	COD removal (percent)	TSS in effluent (milligrams per liter)	Number of samples
05	DE	99	96	5	4
09	A	99	55	4	1
19*	ACD	97		296	360
14*	E	97	91	6	96
10	C	96	82	122	4
16*	BE	96			9
24*	DE	94		28	106
21*	AC	94		147	360
02*	A	93	80	666	360
20	A	93	70	360	4
22*	AC	93	75	197	80
23*	BDE	93	35	18	84
18	D	92	83	2	2
26*	ABCDE	92		177	360
02*	C	91	79	362	360
11*	C	91	85	71	100
08	B	83	57	22	187
01	AC	80			350
15	C	80	73	47	2
25	AC	65	28		2

As noted above, in most industries, process wastewater pollutants are generally proportional to the level of production; however, specification of a percent removal of BOB5 across the wastewater treatment system is a more appropriate basis for this point source category than limitations and standards based on a unit of production. The COD parameter is a secondary control mechanism; the COD percent removal is that which can be expected to occur in the biological wastewater treatment system. However, this does not preclude the use of a physical/chemical wastewater treatment system to attain the equivalent COD reduction.

The variability factor is applied to the long term daily average effluent residual to arrive at the allowable effluent discharge limitations for the daily average mass of BOD5 in any calendar month for a given pharmaceutical plant. This factor for BOD5 is 3.0; the COD variability factor is 2.2. Both the BOD5 and COD variability factors represent the ratio of the 99 percent probability to long term daily average.

Although the BPT regulation published in the FEDERAL REGISTER and supported by this document does not indicate the maximum day limitations for BOD5, COD and TSS, it is expected that the permit writers will handle this issue on a case by case basis. Similarly, those known pollutants, but not identified in this regulation, at a site specific location may be assigned appropriate effluent limitation values by the permit writer using authority of section 402 of the FWPCAA, and in compliance with regulations published in 40 CFR Parts 124 and 125. The constituents contained in the process wastewater vary with the chemical or product produced. Suspended solids are present as a result of most production processes. These may generally be removed by sedimentation basins, clarifiers, filters, centrifuges and evaporation.

(iv) *Treatment and control technology.* Wastewater treatment and control technologies have been studied for this point source category to determine the best practicable control technology currently available.

The following discussion of treatment technology provides the basis for the effluent limitations and guidelines. This discussion does not preclude the selection of other wastewater treatment alternatives which provide equivalent or better levels of treatment.

Pharmaceutical wastewaters vary in quantity and quality depending on the type of manufacturing activities. The wastes from subcategories B, D, and E are more readily treatable than wastes from subcategories A and C, but wastes from all subcategories can be adequately treated in properly designed facilities. The results of an industry survey indicate that a variety of in-plant abatement techniques are utilized by pharmaceutical plants and overall, in-plant wastewater control measures are being practiced throughout the industry. Therefore, these techniques can be incorporated as part of the technology available to meet the limitations. The survey has shown that biological treatment methods are the most prevalent end-of-pipe wastewater treatment systems utilized by the industry.

IN-PLANT POLLUTION ABATEMENT

It is within the manufacturing facility itself that maximum reduction, reuse, and elimination of wastewaters can be accomplished. In-plant practices are the major factor in determining the overall effort required in end-of-pipe wastewater treatment. A complete evaluation of the effectiveness of in-plant processing practices in reducing wastewater pollution requires detailed information on the wastewater flows and pollution concentrations from all types of processing units. Information of a general nature indicates that substantial wastewater pollution reduction through in-plant control is possible. Specific in-plant techniques that are important in controlling waste discharge volumes and pollutant quantities in the pharmaceutical manufacturing point source category are discussed below:

HOUSEKEEPING AND GENERAL PRACTICES

In general, operating and housekeeping practices within the pharmaceutical industry are excellent. The competitive nature of the industry, combined with strict regulations from the Food and Drug Administration, require most producers to operate their plants in the most efficient manner possible. There are numerous examples of good housekeeping practices utilized throughout the industry. A few of the better practices used by exemplary plants are described in the following discussion.

1. All of the plants visited in subcategory D (mixing/compounding and formulation) carried out their routine cleaning most efficiently by vacuum cleaning. Most facilities utilized "house" vacuum systems equipped with bag filters. This practice has resulted in a substantial reduction in the concentration of pollutants and volume of wastewater generated.

2. The use of portable equipment in conjunction with central wash areas is a common practice in many plants throughout the industry. This practice provides better control over the possibility of haphazard dumping of "tail ends" of potentially harmful polluting material to the sewer.

3. Quality control laboratories are an integral part of the pharmaceutical industry, and solvent and toxic substance disposal practices within the laboratories are further evidence of the apparent industry-wide commitment to good housekeeping. Standard practice throughout the industry is to collect toxic wastes and flammable solvents, especially low-boiling-point solvents like ethyl ether, in special waste containers located within the laboratories. Disposal of these wastes varies within the industry, but the most prevalent practice is to have the wastes disposed of by a private contractor or by on-site incineration.

4. Spills of both liquid and solid chemicals, not only inside production areas, but in general plant areas such as roads and loading docks, can lead to water pollution. In most of the pharmaceutical plants visited, a comprehensive spill prevention and cleanup procedures program was an integral part of the plant's good housekeeping procedure. Several plants visited during the survey had excellent spill prevention programs and have significantly reduced the amount of water used for spill cleanup through the use of vacuum collection devices and "squeegees".

5. Stormwater runoff from manufacturing areas, under certain circumstances, contains significant quantities of pollutants. One exemplary technique for controlling such discharges, observed at several plants during the survey visits, consisted of containment and monitoring of stormwater for pH. If the stormwater pH exceeds present limits it is then automatically diverted to the waste treatment facility. Uncontaminated stormwater is discharged without further treatment.

6. The survey indicated that disposal of off-specification batches to the sewer system is not a wide-spread practice because of the high value of the product. Most of the subcategory D plants visited reprocessed their off-specification/liquid formulation batches and either discharged the off-specification solid products to a landfill or reformulated them when possible. Plants in other subcategories, when reprocessing is not possible, either incinerate off-specification batches or collect them in drums and dispose of them via a private disposal contractor.

PROCESS TECHNOLOGY

Many of the newer pharmaceutical plants are being designed with reduction of water use as part of the overall planning and plant design criteria. Improvements which have been implemented in existing plants are primarily dedicated to better control of manufacturing processes and other activities with regard to their environmental aspects. Examples of the kinds of changes which have been implemented within plants surveyed are:

1. The use of barometric condensers can result in significant water contamination, depending upon the nature of the materials entering the discharge water stream. This could be substantially reduced by substituting a heat exchanger for water sprays. As an alternative, several plants are using surface condensers to reduce hydraulic or organic loads.

2. Water-sealed vacuum pumps often create water pollution problems. Several plants are using a sealing water recirculation system as a means of greatly reducing the amount of water being discharged. These systems often require the recycled water to be cooled.

3. The recovery of waste solvents is a common practice among plants using solvents in their manufacturing processes (subcategory A—fermentation products; subcategory C—chemical synthesis products; and to a lesser extent subcategory B—biological products). However, several plants have instituted further measures to reduce the amount of waste solvent discharge. Such measures include incineration of solvents that cannot be recovered economically and "bottoms" from solvent recovery units, and design and construction of solvent recovery columns to strip solvents beyond the economical recovery point.

4. One plant producing a large amount of organic arsenic eliminated the discharge of this toxic substance by recovering the arsenic. Arsenic-laden waste streams are segregated and concentrated before being reused. Non-recoverable arsenic residues are drummed and shipped to an approved landfill.

5. Several techniques have been employed by various subcategory A plants in an effort to reduce the volume of fermentation wastes discharged to end-of-pipe treatment systems. These include concentration of "spent beer" wastes by evaporation, and dewatering and drying of waste mycelia. The resulting dry product in some instances has sufficient economic value as an animal feed supplement to offset a part of the drying cost.

6. One plant has installed automatic COD monitoring instrumentation, and others have utilized pH and TOC monitoring to permit early detection of process upsets which may result in excessive discharges to sewers.

7. Several plants in subcategory B (Biological Extraction Products) segregate the spent eggs used in virus production. The waste plasma and blood fractions used in blood fractionation procedures are likewise separated. They are disposed of by incineration at all plants inspected on field survey.

8. Substitution of chemicals in this industry may be possible; however, the research program required to obtain FDA approval can cost as much as the original studies to obtain approval of the product.

RECYCLE/REUSE PRACTICES

Recycle/reuse can be accomplished either by returning wastewater to its original use, or by using it to satisfy a demand for lower

quality water. The recycle/reuse practices within the pharmaceutical industry are varied and only a few examples are described briefly below:

1. Minimizing the use of once-through cooling water by recycling through cooling towers is used in numerous plants and results in tremendously decreased total wastewater discharge.

2. Dilute waste scrubber waters are collected by one pharmaceutical plant and are used to wash equipment. Although this practice is not applicable to all segments of the industry, it can lead to a substantial reduction in water usage and should be considered in situations where it does not pose a serious threat of product contamination.

3. Several plants reuse waste deionized rinse water for cooling tower makeup.

4. Waste cooling water from one plant was collected in a pond and held as a source of water for fire protection.

AT-SOURCE

The survey indicated that at-source in-plant abatement measures to protect downstream biological treatment plants were practiced by a number of plants within this point source category. Those manufacturing plants utilizing at-source pretreatment were usually found in subcategories A and C. The particular pretreatment processes utilized are discussed below:

CYANIDE DESTRUCTION

The purpose of the cyanide treatment is to reduce high levels of cyanide from raw waste streams by alkaline chlorination prior to discharging the waste into an activated sludge treatment system. The treatment of cyanide wastes by alkaline chlorination involves the addition of chlorine to a waste of high pH. Sufficient alkalinity, usually Ca (OH)2 or NaOH, is added prior to chlorination to bring the waste to a pH of about 11. Violent agitation must accompany the chlorination to prevent the cyanide salt from precipitating out prior to oxidation and hydrolysis. About 7 to 9 pounds each of caustic soda and chlorine are normally required to oxidize one pound of CN to N2 and CO2. However, variation can be expected, depending on the COD and alkalinity of the waste. Destruction of 99.7 percent of cyanide has been achieved by one plant.

Cyanide removal can also be accomplished by electrolytic destruction and by ozonization.

MERCURY REMOVAL

Mercury removal can be accomplished by techniques such as sulfide precipitation, ion exchange, reduction, or adsorption. One manufacturing plant in subcategory C produces a product requiring the use of mercury. The waste from this process contains about 25 mg/l of mercury. In order to protect the biological treatment system utilized to treat the plant's chemical wastes, the mercury-contaminated wastewater is pretreated. Pretreatment consists of exposing the waste to zinc under the proper chemical conditions to permit the amalgamation of the two metals. The mercury concentration has been reduced to less than 5 mg/l. The contents of the holding tank are mixed with other chemical wastes to further reduce the mercury concentration before it is discharged to activated sludge treatment. The mercury-zinc sludge is disposed of by a private disposal contractor.

AMMONIA REMOVAL

Two plants in subcategory C use ammonia compounds in their manufacturing processes resulting in waste streams containing 2.5 to 3.0 percent ammonia. A steam stripping column is utilized to reduce this concentration to about 0.6 percent after which it is mixed with other chemical waste streams to dilute it before treatment by an activated sludge system. The stripped ammonia is returned to the process and reused.

MYCELIA REMOVAL

Based on survey information from more than a dozen fermentation plants, it was determined that many pharmaceutical fermentation plants separate the mycelium by filtration. In addition, some pharmaceutical fermentation product manufacturers have developed an animal feed supplement market for their dried and concentrated waste fermentation broths and waste mycelium. These in-plant abatement measures reduce the raw waste load that otherwise would appear as part of the influent to the biological wastewater treatment plant.

SOLVENT REMOVAL

Recovery of solvents is a common practice of the refining process for a number of antibiotic products in subcategory A as well as synthetic chemicals in subcategory C. Efficient recovery is important in terms of manufacturing cost, as well as reduced waste treatment requirements. Some strong strength solvent wastes are incinerated to reduce the influent raw waste load to the wastewater treatment plant.

SEWER SEGREGATION

In order to provide efficient treatment of the wastes originating within a pharmeceutical plant segregation of concentrated waste streams frequently simplifies waste treatment problems. Wastewaters were often segregated as follows:

1. Strong waste streams.
2. Weak waste streams.
3. Contaminated stormwater from process areas and tank farms.
4. Special wastes such as spent caustics, spent acids, waste solvents, and metal-bearing wastes.
5. Non-contact cooling water.
6. Stormwater drainage streams.

Segregation and incineration of strong waste streams are being practiced by many pharmaceutical plants; however, potential for further segregation still exists. For example, some plants might find that the most cost-effective waste treatment program would include incineration of extremely concentrated wastes, and biological treatment of intermediate strength wastes.

Separation of stormwater runoff is practiced through the industry and, as discussed previously, this practice often facilitates the isolation and treatment of contaminated run-off. The isolation of wastes containing pollutants that may require specialized treatment such as metals, arsenic, ammonia and cyanide is also a demonstrated practice in the pharmaceutical industry which permits effective removal of such pollutants.

Segregation of non-contact cooling water is also practiced within the industry. This practice not only reduces the quantity of wastewater that must be treated, but also facilities water reuse either prior to or after treatment.

END-OF-PIPE CONTROL TECHNOLOGY

In the pharmaceutical manufacturing point source category, end-of-pipe control technology relies heavily upon the use of biological treatment methods. Pretreatment most often consists of equalization basins to minimize shock organic loads, neutralization for pH control and clarifiers to remove solids. The control of pH is sometimes accomplished in separate basins provided for the purpose, but it can be done in equalization basins. In one plant the addition of neutralizing chemicals is done on the basis of monitoring the pH in the activated sludge process itself. Other pretreatment methods observed include cooling of waste and use of roughing filters to reduce organic loadings. Effluent polishing was utilized by many plants, and systems observed included polishing ponds, cascades, and sand filters. Odor control and phosphate removal systems were also observed. One pharmaceutical plant manufacturing subcategory A and C products utilized thermal oxidation and a liquid evaporation process to treat its wastewaters. No activated carbon adsorption systems were observed for pharmaceutical wastewaters; however, there are literature references indicating that this technology is being used in this industry.

Though the present practice is to select a biological treatment method as an end-of-pipe treatment, other treatment techniques are emerging with good potential. Evaporation and the thermal oxidation of strong waste streams are becoming more attractive for those wastewaters which have significant fuel value. In some cases, high fuel requirements would discourage the use of such techniques. Other techniques, including reverse osmosis, ultrafiltration, ozonization, and ion exchange, are being studied and have good potential. For treating strong pharmaceutical wastewater, an activated sludge system using pure oxygen is utilized by a pharmaceutical plant.

EPT COST MODEL

The following is a brief discussion of the treatment technology available and the rationale for selection of the unit processes included.

RATIONALE FOR SELECTION OF UNIT TREATMENT PROCESSES SUBCATEGORIES A, B, C, D, AND E

The raw waste loads for subcategories A and C are significantly higher than other subcategories. The high raw waste loads found in subcategory A are a direct result of the low conversion of raw materials to crude final product. With product yields in the range 1 to 5 percent, it follows that 95 to 99 percent of the raw materials charged to a fermentator become waste products. In subcategory C, refractory raw materials are frequently used in chemical reactors to synthesize complex chemical compounds. Unreacted materials and by-products in subcategory C frequently generate a much harsher raw waste load than is found in subcategory B, which handles naturally occurring substances. Subcategory D raw waste loads tend to be weak in that formulation and packaging operations tend to be dry processes or closely monitored wet processes. The value of the product and FDA regulations preclude the possibility of high raw waste loads from this subcategory. Subcategory E raw waste loads are low due to the fact that the size of the operation is smaller in terms of production since it is research oriented.

Equalization facilities are provided in order to minimize short-interval (e.g., hourly) fluctuations in the organic loading to the treatment plant, as well as to absorb slug loads from reactor cleanouts and accidental spills, and to minimize the usage of neutralization chemicals. On the basis of average flow, two-day detention time is provided for subcategory B, D, and E flows. The large detention time is provided to allow for the hydraulic and organic variability inherent in manufacturing facilities operating less than 24 hours per day and seven days per week. The added detention time will provide for continuous seven days per week operation of the waste-water treatment facilities.

In subcategories A and C the equalization function has been combined with aeration in the four-day aeration basins, which are arranged in at least two cells with provision for optional series or parallel flow.

Depending on the individual plant's product mix, it may be necessary to neutralize the wastewater after equalization to make it more amenable to biological treatment. Neutralization facilities are provided for subcategory A and C wastes; however, neutralization is not required for subcategory B, D and E wastes.

Primary clarification units are included for subcategories A and C; however, they are not included in subcategory B, D, and E facilities because the TSS RWL data indicated it would not be necessary to remove TSS before biological treatment.

For all subcategories, a single-stage activated sludge process was selected because of its demonstrated ability to efficiently treat pharmaceutical wastes. Although a single-stage activated sludge treatment system has been selected for the purpose of developing cost models and if properly operated will allow compliance with these regulations, a multi-stage activated sludge treatment system merits consideration for subcategories A and C. Single-stage processes have provided efficient treatment; however, use of a multi-stage system for subcategories A and C may be desirable for the following reasons:

1. Greater overall removal of BOD.
2. Increased stability and more consistent performance.
3. Greater stability against shock loads.
4. Ability to nitrify in the second stage, resulting in some NH3 removal.

Activated sludge facilities require sludge disposal. In the biological process, for every pound of BOD5 removed from a wastewater, approximately 0.6 pound of TSS (biological solids) is produced which must be removed from the system. Suspended solids may be present as a result of most pharmaceutical processes. These may generally be removed by sedimentation clarification, filtration and centrifugation.

The BPT treatment model proposes sludge disposal by landfilling of the dewatered digested biological sludge with the possibility of utilizing wet sludge in nearby farming operations. If practiced correctly, landfilling of the digested biological sludge does not create health hazards or nuisance conditions. Sludge incineration is a viable alternative, but not included in the treatment model due to high fuel requirements and high cost. Sludge incineration is practiced by some plants where sludge is incinerated along with other solid waste and strong waste streams with high fuel value, reducing the auxiliary fuel requirement to a minimal level. High inert content wastes such as filter cakes which contain heavy metals or corrosives should be placed in a chemical waste landfill. Characteristics of a chemical waste landfill are described in EPA Publication. Landfill Disposal of Hazardous Wastes; A Review of Literature and Known Approaches (EPA/530/SW-165). This publication is available from Solid Waste Information, U.S. EPA, Cincinnati, Ohio 45268.

A summary of the general design basis used to size the unit processes is presented in the Development Document.

Good in-process control is a significant pollution abatement technique for all products processed in the pharmaceutical point source category. Practices such as minimization and containment of spills and leaks, segregation of waste streams, recovery of solvents, monitoring process wastewater, water conservation, water reuse, wastewater equalization and good housekeeping, are necessary to eliminate or reduce the volume of process wastewater requiring treatment.

Some pharmaceutical manufacturing processes are essentially dry, requiring no additional effluent treatment because the existing technology averts the discharge of process wastewater pollutants under normal operating conditions.

If thermal processing (incineration) is the choice for disposal, provisions must be made to ensure against entry of hazardous pollutants into the atmosphere. Consideration should also be given to recovery of materials of value in the wastes.

For those waste materials considered to be nonhazardous where land disposal is the choice for disposal, proper sanitary landfill technology must be followed. The principles set forth in the EPA's Land Disposal of Solid Wastes Guidelines 40 CFR Part 241 may be used as guidance for acceptable land disposal techniques.

(v) *Cost estimates for control of wastewater pollutants.* Capital and annual costs were computed for subcategories A through E on the basis of the hydraulic and biological loading for a wastewater treatment plant applicable to the respective subcategories.

Cost information was obtained directly from industry, engineering firms, equipment suppliers, government sources, and literature. Costs are based on actual industrial installations or engineering estimates for projected facilities as supplied by contributing companies. In the absence of such information, cost estimates have been developed from either plant-supplied costs for similar waste treatment installations at plants making other similar chemicals or general cost estimates for treatment technology.

(vi) *Energy requirements and non-water quality environmental impacts.* Energy requirements associated with treatment and control technologies are not significant when compared to the total energy requirements for this industry. The percent of total operating energy used for wastewater treatment ranged from 3.8 to 7.4 in plants manufacturing products in the A and C subcategories. A major use of treatment plant energy is for sludge incineration: 32 percent of the energy consumed by wastewater treatment plant operation was required for sludge incineration in one case; 78 percent in another case.

Other nonwater quality aspects, such as noise levels, will not be perceptibly affected. Most pharmaceutical plants generate fairly high noise levels [(85–95) dB] within the battery limits because of equipment such as pumps, compressors, steam jets, flare stacks, etc. Equipment associated with in-process or end-of-pipe control systems would not add significantly to these levels.

(vii) Economic and inflationary impact analysis.

Executive Order 11821 (November 27, 1974) requires that major proposals for legislation and promulgation of regulations and rules by Agencies of the executive branch be accompanied by a statement certifying that the inflationary impact of the proposal has been evaluated. The Administrator has directed that all regulatory actions that are likely to result in (1) annualized costs of more than $100 million, (2) additional costs of production more than 5% of the selling price, or (3) an energy consumption increase equivalent to 25,000 barrels of oil per day will require a certified inflationary impact statement. The analysis indicates that the total investment required to meet this regulation is $30.03 million with an annual cost of $9.11 million.

The interim final effluent limitations and guidelines for 1977 will have a minor effect on prices. Price increases of less than 1 percent (range of 0.022 to 0.29 percent) are projected. No plant closures are projected as a result of this regulation; domestic industrial capacity will not be affected. The relatively small price effects are not expected to cause any important international trade effects.

For subcategory E (Research), the added treatment cost represents only 0.03 percent of total industry research and development expenditures; domestic research and development efforts should not be affected by this regulation. Thus the limits presented in these criteria have not been exceeded. However, this analysis satisfies all the requirements for an inflationary impact statement and it is hereby certified that the economic and inflationary effects of this proposal have been carefully evaluated in accordance with Executive Order 11821.

Appendix C—Summary of Public Participation

Prior to this publication, the agencies and groups listed below were consulted and given an opportunity to participate in the development of effluent limitations, guidelines and standards of performance proposed for the pharmaceutical manufacturing point source category. All participating agencies have been informed of project developments. An initial draft of the Development Document was sent to all participants and comments were solicited on that report. The following are the principal agencies and groups consulted: Effluent Standards and Water Quality Information Advisory Committee (established under section 515 of the Act); all State and U.S. Territory Pollution Control Agencies; Academy of Pharmaceutical Sciences; National Institutes of Health; Monsanto Company; Pfizer, Inc.; U.S. Department of Health, Education, and Welfare; E.I. DuPont de Nemours and Company; Allied Chemical Corporation; American Cyanamide Corporation; Lederle Laboratories; National Ecological Research Center; Dow Chemical Company; National Association of Pharmaceutical Manufacturers; Abbott Laboratories; Office of Environmental Affairs; BASF Wyandotte Corporation; Ohio River Valley Sanitation Commission; The Conservation Foundation; Businessmen for the Public Interest; Environmental Defense Fund, Inc.; Natural Resources Defense Council; American Society of Civil Engineers; Water Pollution Control Federation; National Wildlife Federation; American Hospital Association; Smith, Bucklin, and Associates, Inc.; Enviroengineering, Inc.; U.S. Army Environmental Hygiene Agency; Walden Research; American Pharmaceutical Association; Pharmaceutical Manufacturers Association; Manufacturing Chemists Association; New England Interstate Water Pollution Control Commission; American Society of Mechanical Engineers; American Medical Association, Public Health Division; U.S. Water Resources Council; U.S. Department of Defense; U.S. Department of Interior; Eli Lilly and Company; Merck and Company, Inc.; and Parke, Davis and Company.

The following organizations responded with comments for the pharmaceutical manufacturing point source category: Effluent Standards and Water Quality Information Advisory Committee; Abbott Laboratories; Eli Lilly and Company; Merck and Company, Inc.; North Carolina Department of Natural and Economic Resources; United States Department of Defense; Pharmaceutical Manufacturers Association; and United States Department of Interior.

The primary issues raised by commenters during the development of the interim final effluent limitations and guidelines and the response to these comments are as follows:

(1) A commenter did not believe that EPA had the power under section 301 to promulgate effluent limitations for existing sources by regulation. EPA's authority, the commenter felt, is to publish guidelines under section 304(b), which shall be consulted by the permit issuing authority.

Numerous reviewing courts have upheld the position that EPA has the authority and

responsibility to issue national effluent limitations and guidelines pursuant to sections 301 and 304.

(2) In the contractor's draft development document it was suggested that some of the waste disposal problems be turned over to a private disposal contractor. Commenters stated that this is an ineffective way of solving problems unless the contractor is covered by the same guidelines. They said that such contractors should be covered under the category of "miscellaneous chemicals industry."

The suggestion that contract disposal systems are available was not meant to imply that the generator of the wastes is relieved of the responsibility for proper disposal.

(3) Several commenters questioned the rationale used to develop recommended effluent limitations and standards of performance for the Miscellaneous Chemicals Industry presented in February 1975 draft Development Document because the data base was inadequate and the data obtained was improperly interpreted. Specifically, the wide range in the amount of wastes produced per unit of product for any representative list of pharmaceutical products made by medium to large pharmaceutical plants is convincing evidence that the nature of the product and the process rather than production level is the dominant factor. The commenter stated that it is practically and administratively impossible to set quantitative standards for either allowable RWL's or discharges of pollutants per unit of production. Some rational basis for a required percentage reduction of RWL is a better means of regulation.

In response to the several points outlined in this comment the Agency has completely revised the BPT effluent limitations and guidelines. In most cases the actual limitations are based on wastewater treatment efficiencies presently being achieved by the better plants within the category. Estimates were made of raw waste load reductions possible by the use of identified in-plant and end-of-pipe treatment technologies. The effluent reduction capabilities of the identified BPT end-of-pipe treatment were specified on the basis of percent removal across the wastewater treatment plants for each of the five subcategories to eliminate difficulties encountered in the poor correlations between RWLs and production.

(4) Comments were received that stated that RWL's for each subcategory were identified for only one set of products and one production schedule. Further, RWL's were determined on a collective basis for each subcategory—RWL's for the individual products were not determined. Consequently, the commenters concluded that there is no way to determine RWL's for individual products or assess their individual treatability. Furthermore, in the commenters' opinion, subcategorization serves no purpose since there is as much variation of the various parameters within a subcategory as there is between subcategories.

This comment was made when the draft document utilized production based limitations. Since then, this document has been revised and currently uses a percent removal concept across the category. The problems delineated in the comment have been accommodated with the revised approach.

(5) One commenter complained that the process information given is far more than necessary to delineate waste sources, quantities and characteristics.

These regulations do not reveal proprietary or confidential data. However, the Agency must publish enough process background information in the Development Document to show wastes and wastewaters are generated. Furthermore, it is incumbent on the Agency to indicate, where possible, how in-plant pollution abatement methods can reduce end-of-pipe raw waste loads. Frequently, this situation requires a description of the production of crude product or refining options in a general way.

(6) A commenter stated that exemplary is not defined in the document and the commenter is concerned that exemplary parts are those that are high performance treatment plants with no recognition given to the individual circumstances affecting each plant.

A definition will be incorporated into the Development Document supporting this particular point source category. To the extent possible, a full range of plants will be examined in each subcategory.

(7) A commenter indicated that the proposed treatment efficiencies for BPT for BOD5, COD and TOC are either premature and unnecessary or unreasonably high. An industry handling a far more complex waste than the average POTW receives should not be expected to provide substantially greater BOD5 removal.

To require pharmaceutical wastewater treatment plants to achieve higher treatment efficiencies than POTWs is not unreasonable because the operators of POTWs do not know what wastes to expect from day to day and may have less sophisticated equipment. On the other hand a pharmaceutical manufacturer has the design and operational capability to control waste loading and/or the amount of pollution abatement equipment in place. As product mix changes over the years, the pharmaceutical company can change its equipment configurations and wastewater treatment processes to handle new situations.

(8) A common criticism expressed by several commenters was that standards of performance should be based on 99 percent probability of occurrence rather than the 95 percent proposed in the February 1975 draft Development Document.

The regulation has been modified to incorporate this suggestion. To mitigate the possibility of adverse wastewater treatment plant operations, a diversion basin is included in the cost model to handle the probability of encountering high results 2 percent of the time.

(9) A comment stated that it would not be fair to base effluent limitations for a "vertical production" plant on data derived from plants where only one discrete reaction in a "horizontal production" sequence is performed, unless the "vertical production" plant is allowed to claim each of its manufactured derivatives and manufactured raw materials as products on which additional allocations of effluent waste loads may be based.

Under the production based limitations, this commenter had a valid concern. However, under the percent removal concepts each plant is judged on its unique raw waste load for a 12 consecutive month period within the most recent 36 months which shall include the greatest production effort. Hence, the inequities between horizontal and vertical production from plant to plant are not germane. If an individual manufacturing plant changed its internal operations and drastically altered its raw waste load, a permit modification would probably be required.

(10) A commenter indicated that the February 1975 draft Development Document is unclear as to whether animal and feed supplements which are produced using fermentation products technology are appropriately included among these products in subcategory A.

Antibiotics which are produced by the fermentation process and have an end use as additives to animal feed products are included in subcategroy A. By-product mycelium from spent beer is not considered part of the product base used to calculate allowable discharge of pollutants per day.

(11) According to one commenter, thermal oxidation is only one of several methods of disposing of C2 wastes and since only one plant uses this method, he felt that it is patently unrealistic to recommend thermal oxidation as BPT for subcategory C2.

Thermal oxidation for disposing of subcategory C2 wastes has been abandoned in the revised BPT cost model for subcategory C which now includes pharmaceutical products and processes formerly covered in subcategory C2. Since the cost model is used only for developing the economic analysis, this change in the BPT cost model should not be interpreted as discouraging this pollution abatement alternative.

(12) Several commenters were displeased with the long-term average TSS concentrations of 20 mg/l recommended by Roy F. Weston, Inc. the contractor for the 1975 draft Development Document, for subcategories B, C2, D, and E. They expressed the opinion that this concentration is unnecessarily severe considering the highly expensive operating and capital costs of polymer addition for suspended solids flocculation and final clasification facilities.

The proposed BPT TSS limitations for all subcategories were determined by averaging the effluent TSS results from the same group of plants selected for the calculation of the average of the best wastewater treatment plants based on percent removal of BOD5 and by transfer technology. The values are based upon the more recent work of a follow-on contractor, Jacobs Engineering.

(13) A number of commenters have requested an advance copy of the Development Document and guidelines. Most complained that the 30 day comment period is not sufficient.

It is the Agency's position to keep the regulation writing process as open as possible by identifying issues and indicating available options in advance. To this end discussions with industry representatives are being held in advance of this publication in the FEDERAL REGISTER. The use of interim final regulations is necessitated by the court date requiring the publication of a regulation for this industry.

(14) A commenter expressed the opinion that technology transfer is only useful in identifying technology being used in one industry that might have an application in another industry, but it is not a suitable basis for establishing effluent limitations.

Technology transfer has been utilized in previous guideline documents as a rationale for specific waste abatement practices. However, limitations prescribed are based on the application of such transferred technology to the waste waters of the specific industrial category being regulated.

(15) Another commenter noted that other parameters besides BOD, COD and TSS (such as TKN) should have limits applied to them.

The time constraints imposed upon the Agency preclude an exhaustive testing and sampling program for parameters such as TKN at this time. The Agency will continue to study this point source category and supplement parameters in the regulation on an "as needed" basis when sufficient data is available.

(16) A commenter stated that the BPT and BAT in most instances would be insufficient to protect the water quality of the lower flow North Carolina streams involved and the more stringent water-quality determined standards would apply.

The effluent limitations and guidelines presented herein are based on the practicability

and availability of control and treatment technologies. More stringent standards may be applied to a point source, pursuant to section 303 of the Act, when necessary to preserve water quality.

(17) One commenter urged that the U.S. EPA publication "Waste Treatment and Disposal Methods for the Pharmaceutical Industry" by E. J. Struzeski, Jr., should be used in the decision making process when the proposed guidelines are prepared.

This reference publication has been reviewed by both project personnel in the Agency and contractor personnel. Important elements have been extracted and utilized in this regulatory effort.

(18) One commenter requested that subcategorization which includes Class E, Microbiological, Biological and Chemical Research should be deleted and the combination of fermentation and synthesized organic chemicals should be included as a subcategory.

The Agency is requiring the pharmaceutical point source category to install treatment only slightly more sophisticated than is required of municipal dischargers for subcategory E, Research (Microbiological; Biological and Chemical). The slight increment is due to the need to effectively treat test animal and laboratory wastewaters. The Agency has reviewed the option of combining subcategory A (Fermentation Products) and subcategory C (Chemical Synthesis Products). After considerable deliberation a decision has been reached to keep these subcategories separate, since subcategory A has a distinctly different raw waste load in the form of mycelia which is non-existent in subcategory C.

(19) A commenter suggested that dual media filtration should not be mandatory, as its application depends on the specific waste.

It should be understood that the treatment system used in a particular situation is the choice of the individual plant management. Dual-media filtration is well-known and demonstrated technology, currently used in the petroleum refining, grain milling and other industries for effluent solids control. The basic characteristics of the solids in this effluent are amenable to treatment in this way. The Agency has no intention of making dual-media filtration mandatory.

(20) Solvent incineration or recovery should be mandatory at all pharmaceutical plants according to one comment.

The Agency does not have the power to force mandatory solvent incineration or solvent recovery at all pharmaceutical plants. Furthermore, the Agency simply indicates the technology available to achieve BPT limitations and leaves the waste treatment options to the individual plant managers.

(21) A commenter recommended that the metallic ion concentration in any pharmaceutical waste should not be over 2 mg/l.

The Agency has scheduled an intensive review of potentially toxic chemicals which include metallic ions.

(22) A commenter noted that segregation of wastes should not be imposed, as there are cases in which these stream flows are necessary to reduce the concentration of the organic load.

In most cases, it may be advisable to segregate process streams in order to decrease the hydraulic load and thereby decrease the size and cost of pollution control equipment at strategic points within the process or at the front end of a treatment train. It should be stressed that the Agency does not mandate segregation of wastewater streams.

(23) A commenter stated that secondary treatment should not be limited to the activated sludge process. Industries equipped with biofilters should be permitted to operate, even if they would not attain the recommended parameters.

Bio-filters, or for that matter other biological methods, are not meant to be excluded. Activated sludge is presented to provide a baseline cost for the proposed regulations for BPT.

(24) A commentor implied that additional evaluation of the performance of activated sludge plants treating fermenter's slops should be gathered. The 93 percent reduction in these wastes will be very difficult to attain by activated sludge.

The Agency does have evidence that activated sludge plants treating fermenter's slops can attain 94 percent reduction of BOD5 even though this regulation only specifies 90 percent BOD5 removal by the wastewater treatment system.

(25) A commenter stated that consideration should be given to the fact that there are some pharmaceutical wastewaters which are not properly treated by the activated sludge process. This problem has been experienced in plant operations.

The activated sludge plant used in cost model is an example of the type of treatment that can treat the wastewater generated in the manufacture of pharmaceutical products. It is currently in use in this category. EPA has found that eleven of the twenty biological treatment plants visited treated multiple subcategory wastes. The conclusion reached after examining the reductions obtainable with present technology is that 94 percent BOD5 reduction can be reached. Nevertheless, the Agency has selected a 90 percent BOD5 reduction for this interim final regulation in order to reduce potential economic impact. Results from these surveys should identify additional technology that can be used to meet or surpass the effluent limitations. The biological treatment system model used for cost estimating purposes is accepted and used by the manufacturers of pharmaceutical products. Of course, this model is not required technology; the individual plant personnel are responsible for selecting the most effective treatment system applicable in their own case.

(26) A commenter pointed out that consideration should be given to the fact that synthesized chemical production wastewaters are strong, difficult to treat, and frequently inhibitory to biological treatment systems.

In spite of the possibility that subcategory C wastes may have strong and difficult wastes to treat, the data show that an adequately designed and consistently operated standalone treatment plant can achieve 91 percent BOD5 reduction and a combination subcategory A and C wastewater treatment plant can achieve 96 percent BOD5 reduction. It is the judgment of the Agency that the standalone subcategory C plants can apply the necessary technology to achieve the 3 percent improvement required to meet the 94 percent BOD5 reduction. Combination plants are already achieving the 94 percent reduction level. Hence, a 90 percent BOD5 reduction used for this category is reasonable.

(27) One commentor felt that salt concentration in the wastewaters is a matter of importance in some cases and should be discussed more extensively.

The questions of salt concentration is acknowledged and is a part of the continuing study of this subcategory for BAT and NSPS effluent limitations to be proposed in the future.

(28) A commenter stated that design criteria indicated in the Contractor's report is based on an overall basis. The pharmaceutical industry needs individual and pilot plant studies to develop design criteria for the specific wastes.

It should be clearly understood that the treatment system is presented only as a cost model for an average pharmaceutical wastewater treatment plant for the identified subcategory. The Agency does not hold out the cost model configuration as a universal treatment plant, applicable to every plant wastewater within the subcategory. It is acknowledged that a good design procedure would involve pilot plant studies in some cases in order to develop design criteria.

(29) The statement that the wastewaters from the pharmaceutical industry within categories A and C1 may be amenable to sludge incineration because of large quantities of sludge produced should be reviewed according to another commenter.

The Agency is developing additional data in this respect and will expand the discussion of this point at a future date. In any case the individual company would be faced with a cost trade-off between reducing the volume of sludge versus transportation, storage and handling costs of the larger quantity of sludge on an "as is" basis.

(30) A commenter indicated that consideration should be given to the actual hydraulic and organic load of the exemplary plants selected, and then base their performance in terms of these loads.

The contractor is familiar with this kind of analysis and has supplied a table in the revised Development Document which indicates which treatment units are sized on hydraulic load and which use organic load.

(31) One commenter remarked that equalization and neutralization should be used only in those cases where it is necessary, and not included as a required regulation.

Neutralization facilities are included in the cost models for subcategories A and C, but omitted for B, D and E. In the case of equalization facilities, subcategories A and C employ combined equalization and aeration basins with four days residence time. For subcategories B, D and E separate equalization basins are provided in the cost model for each subcategory. It should be emphasized that these recommendations are not mandatory. The management for each plant is free to choose the method of achieving an overall waste load reduction of 90 percent for BOD5 used in this regulation.

A number of other comments were received and were considered not be applicable to the subcategories being promulgated today and have been omitted from the preceding discussion. Appropriate consideration and responses will be made at the time of publication of the regulations applicable to BAT, NSPS and pretreatment (new and existing sources).

Interested persons are encouraged to submit written comments. Comments should be submitted in triplicate to the Environmental Protection Agency, 401 M St., SW., Washington, D.C. 20460, Attention: Distribution Officer, WH-552.

All comments received on or before January 17, 1977, and the availability of the Development Document supporting this interim final regulation will be considered. Steps previously taken by the Environmental Protection Agency to facilitate public response within this time period are outlined in the advance notice concerning public review procedures published on August 6, 1973 (38 FR 21202).

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