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Group II

Development Document for Interim Final Effluent Limitations Guidelines and Proposed New Source Performance Standards for the

PHARMACEUTICAL MANUFACTURING

Point Source Category

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

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DEVELOPMENT DOCUMENT
for
INTERIM FINAL
EFFLUENT LIMITATIONS GUIDELINES
and
PROPOSED NEW SOURCE PERFORMANCE STANDARDS
for the

PHARMACEUTICAL MANUFACTURING
POINT SOURCE CATEGORY

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ABSTRACT

This document presents the findings of a study of the pharmaceutical manufacturing point source category for the purpose of developing effluent limitations and guidelines for existing point sources plus standards of performance and pretreatment standards for existing and new sources, to implement Sections 301(b), 301(c), 304(b), 304(c), 306(b), 306(c), 307(b) and 307(c) of the Federal Water Pollution Control Act, as amended (33 U.S.C. 1251, 1311, 1314(b), 1314(c), 1316(b), 1317(b) and 1317(c), 86 Stat. 816 et. seq.) (the "Act").

Effluent limitations and guidelines contained herein set forth the degree of effluent reduction attainable through the application of the Best Practicable Control Technology Currently Available (BPT) and the degree of effluent reduction attainable through the application of the Best Available Technology Economically Achievable (BAT) which must be achieved by existing point sources by July 1, 1977, and July 1, 1983, respectively. The standards of performance and pretreatment standards for existing and new sources contained herein set forth the degree of effluent reduction which is achievable through the application of the Best Available Demonstrated Control Technology, processes, operating methods, or other alternatives.

The development of data and recommendations in the document relate to the pharmaceutical manufacturing industry, which is one of eight industrial segments of the miscellaneous chemicals industry. Effluent limitations were developed for each subcategory covering the pharmaceutical manufacturing point source category on the basis of the level of raw waste load as well as on the degree of treatment achievable by suggested model systems. These systems include biological and physical/chemical treatment and systems for reduction in pollutant loads.

Supporting data and rationale for development of the proposed effluent limitations, guidelines and standards of performance are contained in this report.

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SECTION I

CONCLUSIONS

General

The miscellaneous chemicals industry encompasses eight segments, grouped together for administrative purposes. This document provides background information for the pharmaceutical manufacturing point source category and represents a revision of a portion of the initial contractor's draft document issued in February, 1975.

In that document it was stated that the pharmaceutical manufacturing point source category differs from the others in raw materials, manufacturing processes, and final products. Water usage and subsequent wastewater discharges also vary considerably from industry to industry. Consequently, for the purpose of the development of the effluent limitations guidelines and corresponding BPT (Best Practicable Control Technology Currently Available), NSPS (Best Available Demonstrated Control Technology) for new sources and BAT (Best Available Technology Economically Achievable) requirements, each category is treated independently.

Technologies have been identified that are expected to produce effluents of recommended quality. Cost estimates have been made for model wastewater treatment plants based upon these technologies. These costs will be used for calculating the economic impact of the guidelines. It must be emphasized that the types of plants identified for this purpose are not to be considered as required nor are they to be construed as the only technology capable of meeting the effluent limitations specified in this development document. The same results can be accomplished by alternative methods which may be more suitable under certain circumstances. These alternative choices include:

1. Various types of end-of-pipe wastewater treatment.
2. Various in-plant modifications and installation of at-source pollution control equipment.
3. Various combinations of end-of-pipe and in-plant technologies.

The extent and complexity of this industry dictated the use of only one treatment model for economic analysis for each subcategory for each effluent level.

Pharmaceutical Manufacturing

The pharmaceutical industry produces hundreds of medicinal chemicals by means of many complex manufacturing technologies. Water usage and subsequent wastewater discharges are closely related to these products and production processes. Any rational approach to effluent limitations and guidelines must recognize these complexities.

For the purpose of establishing effluent limitations, guidelines and standards of performance, the pharmaceutical manufacturing point source category has been divided on the basis of manufacturing techniques, product type, raw materials and wastewater characteristics into five separate subcategories. Factors such as plant size, plant age, geographic location and air pollution control equipment were also considered but did not justify further subcategorization of the point source category. Each of these factors and the related impact on subcategorization are discussed in detail in Section IV. The five subcategories are:

A. Fermentation Products. Most antibiotics and steroids are produced in batch fermentation tanks in the presence of a particular fungus or bacterium and then are isolated by various chemical processes or are simply concentrated or dried.

B. Biological and Natural Extraction Products. Biological and natural extraction products include various blood fractions, vaccines, serums, animal bile derivatives and extracts of plant and animal tissues. These products are usually produced in laboratories on a much smaller scale than most pharmaceutical products.

C. Chemical Synthesis Products. The production of chemical synthesis products is very similar to fine chemicals production. Chemical synthesis reactions generally are batch types which are followed by solvent extraction of the product.

Subcategory C was originally divided into C1 and C2, C1 being production by chemical synthesis alone and C2 being production of an intermediate by fermentation and modification by chemical synthesis. It was concluded, however, that this case could be treated as though the two steps were independent. Hence, the separate C2 classification was abandoned. For consistency in rating the size of a plant for the purpose of estimating the raw waste load, the intermediate obtained from the fermentation process should be counted as a product from the A subcategory and then the modified material should be counted again as a product of the C subcategory.

D. Mixing/Compounding and Formulation. The manufacturing operations for formulation plants may be either dry or wet. Dry production involves dry mixing, tableting or capsuling and packaging. Process equipment is generally vacuum-cleaned to remove dry solids and then washed down. Wet production includes mixing, filtering and bottling. Process equipment is washed down between production batches.

E. Microbiological, Biological and Chemical Research. Research is another important part of the pharmaceutical industry. Although such facilities may not produce specific marketable products, they do generate wastewaters. These originate primarily from equipment and vessel washings and small animal cage washwaters. Large-animal research farms produce significant quantities of manure and urine, which may justify future subclassification of research facilities.

Pharmaceutical plants operate throughout the year. Production processes are primarily batch operations with significant variations in pollutional characteristics over any typical operating period. The characteristics of wastewaters vary from plant to plant according to the raw materials used, the processes used and the products produced. Depending on the product mix and the manufacturing process, variations in wastewater volume and loading may occur as a result of certain batch operations (filter washing, crystallization, solvent extraction, etc.), thus adequate equalization of the waste load may be imperative prior to discharge to a waste treatment system.

Pharmaceutical manufacturing plants use water extensively both in processing and for cooling. The plant wastewater collection systems are often segregated to permit separate collection of process wastewaters and relatively clean non-contact cooling waters. The process wastewaters are usually discharged to a common sewage system for treatment and disposal.

The major sources of wastewaters in the pharmaceutical manufacturing point source category are spent broths or beers from fermentations, residues of reactants and by-products of chemical syntheses, product washings, extraction and concentration procedures, ion exchange regeneration procedures, equipment washdowns and floor washdowns. Wastewaters generated by this point source category can be characterized as containing high concentrations of biochemical oxygen demand (BOD), chemical oxygen demand (COD), volatile and nonvolatile suspended solids and solvents. Wastewaters from some chemical synthesis and fermentation operations may contain heavy metals (Fe, Cu, Ni, Ag, etc.), cyanide, or anti-bacterial constitutents which may exert a toxic effect on biological waste treatment processes. In-plant treatment or pretreatment to remove these constituents may be required at source or before end-of-pipe treatment.

Existing control and treatment technologies, as practiced by the industry, include in-plant abatement as well as end-of-pipe treatment. Recovery and reuse of expensive solvents and catalysts are widely practiced in the pharmaceutical manufacturing point source category for economic reasons. Current end-of-pipe wastewater treatment technology involves biological treatment, physical/chemical treatment, thermal oxidation, or liquid evaporation. Biological treatment includes activated sludge, trickling filters, biofilters and aerated lagoon systems.

The effluent limitations and guidelines proposed herein are based solely on the contaminants in the contact wastewaters associated with the processes previously discussed in the subcategory descriptions. No specific limitations are proposed at this time for pollutants associated with non--contact wastewaters such as boiler and cooling tower blowdown and water supply treatment. Effluent limitations and guidelines for these three streams are being developed in a separate set of regulations for the steam and non-contact cooling water industries.

Since both the raw waste loads (RWL) and the related effluent limitations developed for the pharamceutical manufacturing point source category are based solely on contact process wastewater, it follows that other noncontact wastewaters (including domestic wastes) will not be included in these effluent limitations.

The effluent limitations and guidelines are presented for each of the five subcategories. The wastewater parameters selected are: biochemical oxygen demand (BOD), chemical oxygen demand (COD) and total suspended solids (TSS). The choice of these parameters reflects the fact that organic oxygen-demanding material is the major contaminant in wastewaters generated by the pharmaceutical manufacturing point source category. Ammonia, organic nitrogen, and phosphorus were also found in significant quantities. The best approach to control these pollutants appears to be in-plant measures or at-source treatment in those special cases where excessive discharge is encountered.

Because of extensive in-plant recovery and recycle operations, as described in Section VII, metals and other toxic materials were not found in significant quantities in pharmaceutical plant wastewaters. Other possible RWL parameters (phenol, chlorinated hydrocarbons, various metals, etc.) were considered during the study but were found to be present in concentrations substantially lower than those which would require specialized end-of-pipe treatment for the entire point source category.

It was concluded that the model BPT wastewater treatment technology for subcategories A, B, C, D and E should consist of waste load equalization followed by a biological treatment system with final clarification and sludge handling and treatment facilities. In addition, the subcategory C model should include a trickling filter (or equivalent) and final clarifier following the secondary biological system. The sludge disposal system would generally consist of sludge thickening, aerobic digestion, vacuum filtration and ultimate disposal via landfill. In addition, effluent diversion basins, effluent polishing ponds and neutralization facilities following the biological system would generally be required for those plants falling in subcategories A and C. The term "polishing pond", as used here, means a basin providing a one to two day holding time to permit the maximum removal of suspended solids by sedimentation, but not long enough to grow algae. Additional removal of BOD_5 and COD would also be expected.

The model BAT treatment facility for subcategory A consists of BPT technology followed by trickling filtration, final clarification and multi-media filtration. BAT effluent limitations guidelines for subcategories B, C, D and E are based on the addition of multi-media filtration to the proposed BPT treatment technology. The treatment technology suggested to meet the proposed new source performance standards (NSPS) for subcategories A, B, C, D and E consists of the BPT treatment system plus multi-media filtration.

The data required to develop effluent limitations for specific cases include the identity of the specific manufacturing process, average daily waste flow and raw waste load in terms of BOD_5 and COD, over a sufficient period to be representative for the specific case being evaluated. The mass quantities of influent BOD_5 and COD are then multiplied by their respective percent removal efficiencies and the remainders when multiplied by the appropriate variability factor are expressed as the maximum thirty day limitations which may not be exceeded by the averages computed from daily composite samples taken over a period of 30 consecutive days. This information is sufficient to subcategorize the process and subsequently compute the appropriate effluent limitations.

SECTION II

RECOMMENDATIONS

General

The recommendations for effluent limitations and guidelines commensurate with the BPT and end-of-pipe treatment technology for BPT are presented in this text for the pharmaceutical manufacturing point source category. A discussion of in-plant and end-of-pipe control technology required to achieve the recommended effluent limitations, guidelines and new source performance standards is included.

Pharmaceutical Manufacturing

The effluent limitations and guidelines commensurate with proposed BPT, BAT and NSPS treatment technologies for each subcategory of the pharmaceutical manufacturing point source category are presented in Tables II-1a to II-1e, II-2a to II-2e and II-3a to II-3e. The effluent limitations are based on the average of daily values for 30 consecutive days. Process wastewaters subject to these limitations include all contact process water, but do not include non-contact wastewaters such as boiler and cooling tower blowdown, water treatment wastes, sanitary and other similar flows. The term "sanitary", as herein used, refers to wastewaters from toilets, washrooms, shower baths and food service facilities.

Implicit in the recommended guidelines for the pharmaceutical manufacturing point source category is the fact that process wastes can be isolated from non-process wastes such as utility discharges and uncontaminated storm runoff. Segregation of process from non-process sewers is therefore recommended to accomplish reduction of pollutant loadings to levels necessary to meet the proposed guidelines. Treatment of process wastewaters collected by a combined process/non-process sewer system may not be cost-effective due to dilution by the relatively large volume of nonprocess wastewaters. It is further suggested that normally uncontaminated waters, such as storm runoff, be segregated if it flows from outdoor areas where there is potential for contamination by chemical spills. This could be accomplished by roofing or curbing potentially contaminated areas and by collecting and treating runoff which cannot be isolated from such areas. In-plant modification which will lead to reductions in wastewater flow, increased quantity of water used for recycle or reuse and improvement in raw wastewater quality should be implemented, provided that these modifications have minimum impact on processing techniques or product quality. In some cases, segregation of strong and weak waste streams and treating them separately is recommended from the standpoint of cost-effectiveness.

For wastewater containing significant quantities of metals, cyanide, or anti-bacterial constituents which may exert a toxic effect on biological treatment processes, pretreatment at source is recommended. For those wastewaters which contain significant quantities of cyanide or ammonia, cyanide destruction or ammonia removal at source is recommended. Ammonia stripping is well demonstrated technology. Other in-plant measures, such as solvent recovery and incineration (of still bottoms and of solvent streams that are too impure to reuse) are practiced by many pharmaceutical plants and are recommended for adoption by all plants where applicable. This technique could result in a more cost-effective disposal of organic liquids that are too strong for effective biological treatment.

End-of-pipe treatment technologies equivalent to biological treatment should be applied to the wastewaters from all of the subcategories to achieve BPT effluent requirements. In addition, to minimize capital expenditures for end-of-pipe wastewater treatment facilities, BPT technology includes the maximum utilization of current in-plant pollution abatement methods presently practiced by the pharmaceutical manufacturing point source category.

To limit the release of high TSS, BOD and COD in the final discharge, effluent polishing ponds and diversion basins are recommended for treatment plants in the A and C subcategories. In recognition of the greater complexity and variability of subcategory C wastes the BPT model for this subcategory includes a tertiary stage comprising a trickling filter and two final clarifiers.

To meet BAT requirements, end-of-pipe treatment technologies equivalent to BPT treatment, followed by trickling filtration, final clarification and multi-media filtration are recommended for subcategory A. For subcategories B, C, D and E, BPT treatment followed by multi-media filtration is proposed. BAT treatment technology also includes the improvement of existing in-plant pollution abatement measures and the use of the most exemplary process controls.

TSS limitations for BPT are expressed as concentrations which can be reasonably attained by treatment models described in the document. TSS limitations for BAT and NSPS are expressed as concentrations which, by technology transfer, appear reasonably attainable with multi-media filtration shown for all subcategories, supplemented by diversion basins in the A and C models.

NSPS control and treatment standards, to be applied to new sources, are equivalent to BPT treatment followed by multi-media filtration. This is identical to BAT standards for subcategories B, C, D and E. Exemplary in-process controls are also applicable to this technology. The treatment, control theory and effluent limitations for the non-process wastewaters (boiler blowdown, cooling tower blowdown, water supply treatment plant wastes) generated by the pharmaceutical manufacturing point source category should be covered by the steam supply and non-contact cooling water point source category regulations which are to be published by EPA.

TABLE II-1a

BPT EFFLUENT LIMITATIONS AND GUIDELINES

Subcategory A - Fermentation Products Subcategory

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:

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% reduction in the long term daily average raw waste content of BOD5 multiplied by a variability factor of 3.0.

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% reduction in the long term daily average raw waste content of COD multiplied by a variability factor of 2.2.

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.

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 separable mycelia and solvents in those raw waste loads; provided that residual amounts of mycelia 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 separable 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.

The pH shall be within the range of 6.0 - 9.0 standard units.

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BPT EFFLUENT LIMITATIONS AND GUIDELINES

Subcategory B - Extraction Products Subcategory

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.

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

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

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.

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.

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

The pH shall be within the range of 6.0 - 9.0 standard units.

TABLE II - 1c

BPT EFFLUENT LIMITATIONS AND GUIDELINES

Subcategory C - Chemical Synthesis Products Subcategory

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.

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

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

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.

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.

The pH shall be within the range of 6.0 - 9.0 standard units.

TABLE II - 1d

BPT EFFLUENT LIMITATIONS AND GUIDELINES

Subcategory D - Mixing/Compounding and Formulation Subcategory

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.

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

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

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.

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.

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

The pH shall be within the range of 6.0 - 9.0 standard units.

BPT EFFLUENT LIMITATIONS AND GUIDELINES

Subcategory E - Research Subcategory

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 research effort for a given pharmaceutical plant.

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

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

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.

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.

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

The pH shall be within the range of 6.0 - 9.0 standard units.

TABLE II-2a

BAT EFFLUENT LIMITATIONS AND GUIDELINES

Subcategory 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:

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 97% reduction in the long term daily average raw waste content of BOD5 multiplied by a variability factor of 3.0.

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 80% reduction in the long term daily average raw waste content of COD multiplied by a variability factor of 2.2.

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.

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 separable mycelia and solvents in those raw waste loads; provided that residual amounts of mycelia 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 separable 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.

The pH shall be within the range of 6.0 - 9.0 standard units.

TABLE II - 2b

BAT EFFLUENT LIMITATIONS AND GUIDELINES
SUBCATEGORY B

The allowable effluent discharge limitation for the daily average mass of BOD5 in any calendar month shall specifically reflect not less than 91% reduction in the long term daily average raw waste content of BOD5 multiplied by a variability factor of 3.0.

The allowable effluent discharge limitation for the daily average mass of COD in any calendar month shall specifically reflect not less than 75% reduction in the long term daily average raw waste content of COD multiplied by a variability factor of 2.2.

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.

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.

The average of daily TSS values for any calendar month shall not exceed 30 mg/l.

The pH shall be within the range of 6.0 - 9.0 standard units.

TABLE II - 2c

BAT EFFLUENT LIMITATIONS AND GUIDELINES
SUBCATEGORY C

The allowable effluent discharge limitation for the daily average mass of BOD5 in any calendar month shall specifically reflect not less than 97% reduction in the long term daily average raw waste content of BOD5 multiplied by a variability factor of 3.0.

The allowable effluent discharge limitation for the daily average mass of COD in any calendar month shall specifically reflect not less than 80% reduction in the long term daily average raw waste content of COD multiplied by a variability factor of 2.2.

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.

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.

The pH shall be within the range of 6.0 - 9.0 standard units.

TABLE II - 2d

BAT EFFLUENT LIMITATIONS AND GUIDELINES
SUBCATEGORY D

The allowable effluent discharge limitation for the daily average mass of BOD5 in any calendar month shall specifically reflect not less than 91% reduction in the long term daily average raw waste content of BOD5 multiplied by a variability factor of 3.0.

The allowable effluent discharge limitation for the daily average mass of COD in any calendar month shall specifically reflect not less than 75% reduction in the long term daily average raw waste content of COD multiplied by a variability factor of 2.2.

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.

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.

The average of daily TSS values for any calendar month shall not exceed 30 mg/l.

The pH shall be within the range of 6.0 - 9.0 standard units.

TABLE II - 2e

12/6/76

BAT EFFLUENT LIMITATIONS AND GUIDELINES
SUBCATEGORY E

The allowable effluent discharge limitation for the daily average mass of BOD5 in any calendar month shall specifically reflect not less than 91% reduction in the long term daily average raw waste content of BOD5 multiplied by a variability factor of 3.0.

The allowable effluent discharge limitation for the daily average mass of COD in any calendar month shall specifically reflect not less than 75% reduction in the long term daily average raw waste content of COD multiplied by a variability factor of 2.2.

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.

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.

The average of daily TSS values for any calendar month shall not exceed 30 mg/l.

The pH shall be within the range of 6.0 - 9.0 standard units.

TABLE II-3a

NSPS EFFLUENT LIMITATIONS AND GUIDELINES

Subcategory 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:

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 91% reduction in the long term daily average raw waste content of BOD5 multiplied by a variability factor of 3.0.

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 76% reduction in the long term daily average raw waste content of COD multiplied by a variability factor of 2.2.

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.

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 separable mycelia and solvents in those raw waste loads; provided that residual amounts of mycelia 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 separable 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.

The pH shall be within the range of 6.0 - 9.0 standard units.

TABLE II - 3b

NSPS EFFLUENT LIMITATIONS AND GUIDELINES
SUBCATEGORY B

The allowable effluent discharge limitation for the daily average mass of BOD5 in any calendar month shall specifically reflect not less than 91% reduction in the long term daily average raw waste content of BOD5 multiplied by a variability factor of 3.0.

The allowable effluent discharge limitation for the daily average mass of COD in any calendar month shall specifically reflect not less than 75% reduction in the long term daily average raw waste content of COD multiplied by a variability factor of 2.2.

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.

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.

The average of daily TSS values for any calendar month shall not exceed 30 mg/l.

The pH shall be within the range of 6.0 - 9.0 standard units.

TABLE II - 3c

NSPS EFFLUENT LIMITATIONS AND GUIDELINES
SUBCATEGORY C

The allowable effluent discharge limitation for the daily average mass of BOD5 in any calendar month shall specifically reflect not less than 91% reduction in the long term daily average raw waste content of BOD5 multiplied by a variability factor of 3.0.

The allowable effluent discharge limitation for the daily average mass of COD in any calendar month shall specifically reflect not less than 76% reduction in the long term daily average raw waste content of COD multiplied by a variability factor of 2.2.

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.

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.

The pH shall be within the range of 6.0 - 9.0 standard units.

TABLE II - 3d

NSPS EFFLUENT LIMITATIONS AND GUIDELINES SUBCATEGORY D

The allowable effluent discharge limitation for the daily average mass of BOD5 in any calendar month shall specifically reflect not less than 91% reduction in the long term daily average raw waste content of BOD5 multiplied by a variability factor of 3.0.

The allowable effluent discharge limitation for the daily average mass of COD in any calendar month shall specifically reflect not less than 75% reduction in the long term daily average raw waste content of COD multiplied by a variability factor of 2.2.

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.

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.

The average of daily TSS values for any calendar month shall not exceed 30 mg/l.

The pH shall be within the range of 6.0 - 9.0 standard units.

TABLE II - 3e

NSPS EFFLUENT LIMITATIONS AND GUIDELINES
SUBCATEGORY E

The allowable effluent discharge limitation for the daily average mass of BOD5 in any calendar month shall specifically reflect not less than 91% reduction in the long term daily average raw waste content of BOD5 multiplied by a variability factor of 3.0.

The allowable effluent discharge limitation for the daily average mass of COD in any calendar month shall specifically reflect not less than 75% reduction in the long term daily average raw waste content of COD multiplied by a variability factor of 2.2.

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.

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.

The average of daily TSS values for any calendar month shall not exceed 30 mg/l.

The pH shall be within the range of 6.0 - 9.0 standard units.

SECTION III

INTRODUCTION

Purpose and Authority

The Federal Water Pollution Control Act Amendments of 1972 (the Act) made a number of fundamental changes in the approach to achieving clean water. One of the most significant changes was to shift from a reliance on effluent limitations related to water quality to a direct control of effluents through the establishment of technology-based effluent limitations to form an additional basis, as a minimum, for issuance of discharge permits.

The Act requires EPA to establish guidelines for technology-based effluent limitations which must be achieved by point sources of discharges into the navigable waters of the United States. 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 are based on the application of the BPT 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 are based on the application of the BAT, resulting in 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 306 of the Act requires the achievement by new sources of federal standards of performance providing for the control of the discharge of pollutants, which reflects the greatest degree of effluent reduction which the Administrator determines to be achievable through the application of the NSPS process, operating methods, or other alternatives, including, where practicable, a standard permitting no discharge of pollutants.

Section 304(b) of the Act requires the Administrator to publish regulations based on the degree of effluent reduction attainable through the application of the BPT and the best control measures and practices achievable, including treatment techniques, process and procedure innovations, operation methods and other alternatives. The regulations proposed herein set forth effluent limitations guidelines pursuant to Section 304(b) of the Act for the pharmaceutical manufacturing point source category. Section

304(c) of the Act requires the Administrator to issue information on the processes, procedures, or operating methods which result in the elimination or reduction in the discharge of pollutants to implement standards of performance under Section 306 of the Act. Such information is to include technical and other data, including costs, as are available on alternative methods of elimination or reduction of the discharge of pollutants.

Section 306 of the Act requires the Administrator, within one year after a category of sources is included in a list published pursuant to Section 306(b) (1) (A) of the Act, to propose regulations establishing federal standards of performance for new sources within such categories. The Administrator published in the Federal Register of January 16, 1973 (38 F.R. 1624) a list of 27 source categories. Publication of the list constituted announcement of the Administrator's intention of establishing, under Section 306, standards of performance applicable to new sources.

Furthermore, Section 307(b) provides that:

1. The Administrator shall, from time to time, publish proposed regulations establishing pretreatment standards for introduction of pollutants into treatment works (as defined in Section 212 of this Act) which are publicly owned, for those pollutants which are determined not to be susceptible to treatment by such treatment works or which would interfere with the operation of such treatment works. Not later than ninety days after such publication and after opportunity for public hearing, the Administrator shall promulgate such pretreatment standards. Pretreatment standards under this subsection shall specify a time for compliance not to exceed three years from the date of promulgation and shall be established to prevent the discharge of any pollutant through treatment works (as defined in Section 212 of this Act) which are publicly owned, which pollutant interferes with, passes through, or otherwise is incompatible with such works.

2. The Administrator shall, from time to time, as control technology, processes, operating methods, or other alternatives change, revise such standards, following the procedure established by this subsection for promulgation of such standards.

3. When proposing or promulgating any pretreatment standard under this section, the Administrator shall designate the category or categories of sources to which such standard shall apply.

4. Nothing in this subsection shall affect any pretreatment requirement established by any State or local law not in conflict with any pretreatment standard established under this subsection.

In order to insure that any source introducing pollutants into a publicly owned treatment works, which would be a new source subject to Section 306 if it were to discharge pollutants, will not cause a violation of the effluent limitations established for any such treatment works, the Administrator shall promulgate pretreatment standards for the category of such sources simultaneously with the promulgation of standards of performance under Section 306 for the equivalent category of new sources. Such pretreatment standards shall prevent the discharge into such treatment works of any pollutant which may interfere with, pass through, or otherwise be incompatible with such works.

The Act defines a new source to mean any source the construction of which is commenced after the publication of proposed regulations prescribing a standard of performance. Construction means any placement, assembly, or installation of facilities or equipment (including contractual obligations to purchase such facilities or equipment) at the premises where such equipment will be used, including preparation work at such premises.

Standard Industrial Classifications

The Standard Industrial Classifications list was developed by the United States Department of Commerce and is oriented toward the collection of economic data related to gross production, sales, and unit costs. The SIC list is not related to the nature of the industry in terms of actual plant operations, production, or considerations associated with water pollution control. As such, the list does not provide a realistic or definitive set of boundaries for study of the pharmaceutical manufacturing industry.

The other commodities/services which could have been considered for coverage within the pharmaceutical manufacturing point source category of the miscellaneous chemicals industry study but were not covered under the scope of this study as defined by EPA are:

SIC 2844 - Cosmetic Preparations
SIC 3842 - Surgical Supplies
SIC 3843 - Dental Supplies
SIC 8071 - Medical Laboratories
SIC 8072 - Dental Laboratories
SIC 8081 - Out-patient Care Facilities
SIC 8091 - Health and Allied Services, not elsewhere classified

Effluent limitations and guidelines may be developed at a later date to cover these commodities/services not covered under the present study.

<u>Methods Used for Development of the Effluent Limitations and Standards for Performance</u>

The effluent limitations, guidelines and standards of performance proposed in this document were developed in the following manner. The miscellaneous chemicals industry was first divided into industrial segments, based on type of industry and products manufactured. Determination was then made as to whether further subcategorization would aid in description of the industry. Such determinations were made on the basis of raw materials required, products manufactured, processes employed and other factors.

The raw waste characteristics for each category and/or subcategory were then identified. This included an analysis of: 1) the source and volume of water used in the process employed and the sources of wastes and wastewaters in the plant; and 2) the constituents of all wastewaters (including potentially toxic constituents) which result in taste, odor and color in water. The constituents of wastewaters which should be subject to effluent limitations, guidelines and standards of performance were identified.

The full range of control and treatment technologies existing within each category and/or subcategory was identified. This included an identification of each distinct control and treatment technology, including both in-plant and end- of-pipe technologies, which are existent or capable of being designed for each subcategory or category. It also included an identification of the effluent level resulting from the application of each of the treatment and control technologies, in terms of the amount of constituents and of the chemical, physical and biological characteristics of pollutants. The problems, limitations and reliability of each treatment and control technology and the required implementation time were also identified. In addition, the non-water quality environmental impacts (such as the effects of the application of such technologies upon other pollution problems, including air, solid waste, radiation and noise) were also identified. The energy requirements of each of the control and treatment technologies were identified, as well as the cost of the application of such technologies.

The information, as outlined above, was then evaluated in order to determine what levels of technology constituted the BPT, BAT and NSPS. In identifying such technologies, factors considered included the total cost of application of technology in relation to the effluent reduction benefits to be achieved from such application, the age of equipment and facilities involved, the process employed, the engineering aspects of the application of various types of control techniques, process changes, non-water quality environmental impact (including energy requirements) and other factors.

During the initial phases of the study, an assessment was made of the availability, adequacy and usefulness of all existing data sources. Data on the identity and performance of wastewater treatment systems were known to be included in:

1. NPDES permit applications.

2. Self-reporting discharge data from various states.

3. Surveys conducted by trade associations or by agencies under research and development grants.

A preliminary analysis of these data indicated an obvious need for additional information.

Additional data in the following areas were required: 1) process raw waste load (RWL) related to production; 2) currently practiced or potential in-process waste control techniques; and 3) the identity and effectiveness of end-of-pipe treatment systems. The best source of information was the manufacturers themselves. New information was obtained from direct interviews and sampling visits to production facilities.

Collection of the data necessary for development of RWL and effluent treatment capabilities within dependable confidence limits required analysis of both production and treatment operations. In a few cases, the plant visits were planned so that the production operations cf a single plant could be studied in association with an end-of-pipe treatment system which receives only the wastes from a single production process. The RWL for this plant and associated treatment technology would fall within a single subcategory. However, the wide variety of products manufactured by most of the industrial plants made this situation rare.

In the majority of cases, it was necessary to visit individual facilities where the products manufactured fell into several subcategories. The end-of-pipe treatment facilities received combined wastewaters associated with several subcategories (several products, processes, or even unrelated manufacturing operations). It was necessary to analyze separately the production (waste-generating) facilities and the effluent (waste treatment) facilities. This approach required establishment of a common basis, the raw waste load (RWL), for common levels of treatment technology for the products within a subcategory and for the translation of treatment technology between categories and/or subcategories.

The selection of treatment plants was developed from information available in the NPDES permit applications, state self-reporting discharge data and contacts within the industry. Every effort was made to choose facilities where meaningful information on both treatment facilities and manufacturing processes could be obtained.

Survey teams composed of project engineers and scientists conducted the actual plant visits. Information on the identity and performance of wastewater treatment systems was obtained through:

1. Interviews with plant water pollution control personnel or engineering personnel.

2. Examination of treatment plant design and historical operating data (flow rates and analyses of influent and effluent).

3. Treatment plant influent and effluent sampling.

Information on process plant operations and the associated RWL was obtained through:

1. Interviews with plant operating personnel.

2. Examination of plant design and operating data (original design specification, flow sheets, day-to-day material balances around individual process modules or unit operations where possible).

Table III -1

Biological Products - SIC 2831

Agar culture media
Aggressins
Allergenic extracts
Allergens
Antigens
Anti-hog-cholera serums
Antiserums
Antitoxins
Antivenom
Bacterial vaccines
Bacterins
Bacteriological media
Biological and allied products: antitoxins, bacterins, vaccines, viruses
Blood derivatives, for human or veterinary use
Culture media or concentrates
Diagnostic agents, biological
Diphtheria toxin
Plasmas
Pollen extracts
Serobacterins
Serums
Toxins
Toxoids
Tuberculins
Vaccines
Venoms
Viruses

Table III -2

Medicinal Chemicals and Botanical Products - SIC 2833

Adrenal derivatives: bulk, uncompounded
Agar-agar (ground)
Alkaloids and salts
Anesthetics, in bulk form
Antibiotics: bulk uncompounded
Atropine and derivatives
Barbituric acid and derivatives: bulk, uncompounded
Botanical products, medicinal: ground, graded, and milled
Brucine and derivatives
Caffeine and derivatives
Chemicals, medicinal: organic and inorganic--bulk, uncompounded
Cinchone and derivatives
Cocaine and derivatives
Codeine and derivatives
Digitoxin
Drug grading, grinding, and milling
Endocrine products
Ephedrine and derivatives
Ergot alkaloids
Fish liver oils, refined and concentrated for medicinal use
Gland derivatives: bulk, uncompounded
Herb grinding, grading, andmilling
Hormones and derivatives
Insulin: bulk, uncompounded
Kelp plants
Mercury chlorides, U.S.P.
Mercury compounds, medicinal: organic and inorganic
Morphine and derivatives
N-methylpiperazine
Oils, vegetable and animal: medicinal grade--refined and concentrated
Opium derivatives
Ox bile salts and derivatives: bulk, uncompounded
Penicillin: bulk, uncompounded
Physostigmine and derivatives
Pituitary gland derivatives: bulk, uncompounded
Procaine and derivatives: bulk, uncompounded
Quinine and derivatives
Reserpines
Salicylic acid derivatives, medicinal grade
Strychnine and derivatives
Sulfa drugs
Sulfonamides
Theobromine
Vegetable gelatin (agar-agar)
Vegetable oils, medicinal grade: refined and concentrated
Vitamins, natural and synthetic: bulk, uncompounded

Table III -3

Pharmaceutical Products - SIC 2834

Adrenal pharmaceutical preparations
Analgesics
Anesthetics, packaged
Antacids
Anthelmintics
Antibiotics, packaged
Antihistamine preparations
Antipyretics
Antiseptics, medicinal
Astringents, medicinal
Barbituric acid pharmaceutical preparations
Belladonna pharmaceutical preparations
Botanical extracts: powdered, pilular, solid, and fluid
Chapsticks
Chlorination tablets and kits (water purification)
Cold remedies
Cough medicines
Cyclopropane for anesthetic use (U.S.P. par N.F.) packaged
Dextrose and sodium chloride injection mixed
Dextrose injection
Digitalis pharmaceutical preparations
Diuretics
Druggists' preparations (pharmaceuticals)
Effervescent salts
Emulsifiers, fluorescent inspection
Emulsions, pharmaceutical
Ether for anesthetic use
Fever remedies
Galenical preparations
Hormone preparations
Insulin preparations
Intravenous solutions
Iodine, tincture of
Laxatives
Liniments
Lozenges, pharmaceutical
Medicines, capsuled or ampuled
Nitrofuran preparations
Nitrous oxide for anesthetic use
Ointments
Parenteral solutions
Penicillin preparations
Pharmaceuticals
Pills, pharmaceutical
Pituitary gland pharmaceutical preparations
Poultry and animal remedies
Powders, pharmaceutical
Procaine pharmaceutical preparations
Proprietary drug products
Remedies, human and animal
Sirups, pharmaceutical
Sodium chloride solution for injection U.S.P.
Sodium salicylate tablets
Solutions, pharmaceutical
Spirits, pharmaceutical
Suppositories
Tablets, pharmaceutical
Thyroid preparations
Tinctures, pharmaceutical
Tranquilizers and mental drug preparations
Vermifuges
Veterinary pharmaceutical preparations
Vitamin preparations
Water decontamination or purification tablets
Water, sterile: for injections
Zinc ointment

3. Individual process wastewater sampling and analysis.

The data base obtained in this manner was then utilized by the methodology previously described to develop recommended effluent limitations and standards of performance for the pharmaceutical manufacturing point source category. All of the references utilized are included in Section XV of this report. The data obtained during the field data collection program are included in Supplement B. Cost information is available in Supplement A. The documents are available for examination by interested parties at the EPA Public Information Reference Unit, Room 2922 (EPA Library), Waterside Mall, 401 M St., S.W., Washington, D.C. 20460.

The following text describes the details of the scope of the study, the technical approach to the development of effluent limitations and the scope of coverage for the data base for the pharmaceutical manufacturing pcint source category.

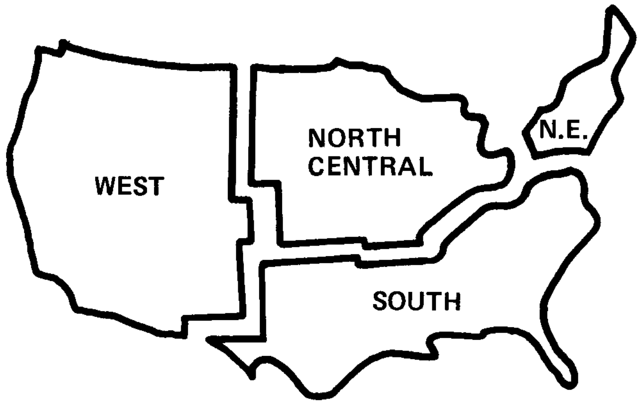
Pharmaceutical Manufacturing

Scope of the Study

To establish boundaries for the scope of work for this study, the pharmaceutical manufacturing point source category was defined to include all commodities listed under SIC 2831 (Biological Products), SIC 2833 (Medicinal Chemicals and Botanical Products) and SIC 2834 (Pharmaceutical Preparations). Lists of the specific products covered by these Standard Industrial Classifications are presented in Tables III-1, III-2 and III-3. It should be noted that the lists as provided in these tables were developed by the United States Department of Commerce and are oriented toward the collection of economic data related to gross production, sales and unit costs. They are not related to actual plant operations, production, or considerations associated with water pollution control and, as such, they do not provide a precise set of boundaries which is completely applicable for this type of study of the pharmaceutical industry. Therefore, to establish effluent limitations and treatment guidelines for this industry, a more definitive set of boundaries was established. To accomplish this, SIC 2833 was further subdivided into fermentaticn products, chemical synthesis products and extraction products. This additional subdivision was required to establish a consistent interrelationship between the major manufacturing processes employed by the pharmaceutical industry and the major medicinal chemical groups produced by the industry. During

FIGURE III -1*

SHIPMENTS OF PHARMACEUTICAL PREPARATIONS
BY CENSUS REGIONS, DIVISIONS AND STATES, 1967



REGION	SHIPMENTS OF PHARMACEUTICAL PREPARATIONS, EXCEPT BIOLOGICALS (MILLIONS OF DOLLARS)	PERCENT OF U.S.
NORTHEAST	$2,457.7	59.3%
NEW YORK	789.3	
NEW JERSEY	887.6	
PENNSYLVANIA	709.0	
OTHER	71.8	
NORTH CENTRAL	1,287.3	31.1
OHIO	94.1	
INDIANA	425.6	
ILLINOIS	303.5	
MICHIGAN	300.9	
MISSOURI	99.6	
OTHER	63.6	
SOUTH	292.2	7.1
SOUTH ATLANTIC	177.9	
EAST SOUTH CENTRAL	87.5	
WEST SOUTH CENTRAL	26.8	
WEST	104.2	2.5
CALIFORNIA	97.9	
OTHER	06.3	
U.S. TOTAL	$4,143.0	100.0%

*PRESECRPTION DRUG INDUSTRY FACT BOOK, PMA, 1973 the course of the study, the following four major production areas were identified for in-depth study:

A. Fermentation processes: used to produce primarily antibiotics and steroids.

B. Biological products and natural extractions manufacturing processes: used to produce blood derivatives, vaccines, serums, animal bile derivatives, animal tissue derivatives and plant tissue derivatives.

C. Chemical synthesis processes: used to produce hundreds of different products, from vitamins to anti-depressants.

D. Formulation processes: used to convert the products of the other three manufacturing areas into the final dosage forms (tablets, capsules, liquids, etc.) marketed to the public.

In addition, since research is such a discrete and important part of the pharmaceutical industry, a fifth study area was established:

E. Research: including microbiological, biological and chemical research activities.

A further subdivision of subcategory E was considered, which may be described as research farms. Animals ranging in size from poultry to cows and horses are held for the experimental use of drugs to control disease or promote growth, ovulation or other desirable effects. The excreta of such animals are usually disposed of by methods common in the farming community. The examination of pollution control measures in this area may be taken up at a later time.

Technical Approach to the Development of Effluent Limitations Guidelines

The effluent limitations and standards of performance recommended in this document for the pharmaceutical manufacturing point source category were developed in the manner outlined in the section "Methods Used for Development of Effluent Limitations and Standards of Performance" above.

Scope of Coverage for Data Base

Figure III-1 illustrates the geographical breakdown of the pharmaceutical manufacturing industry in the continental

FIGURE III -2a

PROFILE OF 45 MAJOR PHARMACEUTICAL COMPANIES

Company	Annual Sales 1975 $MM	No. of Empl.	Facility Profile (Based on Product Slate)				
			A	B	C	D	E
Abbott Laboratories North Chicago, Ill.	940.7	22,829					
North Chicago			X	X	X	X	X
Wichita, Kansas					X		
Universal Enterprises, Barceloneta, P. Rico			X		X	X	
Rocky Mountain, N.C.					X	X	
Ross Laboratories, Columbus, Ohio					X	X	X
American Cyanamid Co. Wayne, N. J.	1,900	38,024					
Azusa, California					X		
Bound Brook, N. J.					X	X	
Hannibal, Mo.			X		X	X	X
Lederle Laboratories, Pearl River, N.Y.			X	X	X	X	X
Willow Island, W. VA.					X	X	
Princeton, N.J.							X
Manati, P. Rico					X	X	
Hoechst-Roussell Pharm. Somerville, N.J.					X	X	X
American Home Products Corp., N.Y., N.Y.	2,258.6	45,703					
Wyeth Laboratories, Inc. Paoli, Pa.				X	X	X	X
Ayerst Laboratories					X	X	X
Astra Pharmaceutical Products, Inc. Worcester, Mass.						X	X

FIGURE III -2b

PROFILE OF 45 MAJOR PHARMACEUTICAL COMPANIES

Company	Annual Sales 1975 $MM	No. of Empl.	Facility Profile (Based on Product Slate)				
			A	B	C	D	E
Baxter Laboratories, Inc. Morton Grove, Ill.	560	19,700					
Travenol Laboratories, Inc., Los Angeles, CA				X	X	X	X
Wallerstein Co. D.' W. Deerfield, Ill.							
Cleveland, Miss.				X	X	X	
Kingstree, S. C..			X	X	X	X	X
Puerto Rico						X	
Alcon Laboratories Fort Worth, Tex.	60	1,789			X	X	X
Owens Laboratories							
Center Laboratories							
Chicago Pharmacal Co.							
William A. Webster Co.							
Barry Laboratories, Inc. Pompano Beach, Fla.				X	X	X	X
Beecham, Inc. Clifton, N. J.							
Clifton, N. J.					X	X	
Beecham Labs. Bristol, Tenn.					X	X	X
Piscataway, N. J.							
Bristol Myers Co. New York, N. Y.	1,827.7	29,700					
Bristol Myers Industrial Div. Syracuse, N. Y.			X		X	X	X
Bristol Myers Products Hillside, N. J.					X	X	X
Mead, Johnson & Co. Evansville, Ind.					X	X	X

FIGURE III -2c

PROFILE OF 45 MAJOR PHARMACEUTICAL COMPANIES

Company	Annual Sales 1975 $MM	No. of Empl.	Facility Profile (Based on Product Slate)				
			A	B	C	D	E
Bristol Myers Industrial							
Barceloneta, P. Rico							
Bristol Labs. Corp.					X	X	
Mayaguez, P. Rico							
Westwood Pharma.					X	X	X
Buffalo, N. Y.							
Ciba-Geigy Corp.							
Summit, N. J.							
Summit, N. J.					X	X	X
Suffern, N. Y.					X	X	X
McIntosh, Ala.					X	X	X
CPC International Inc.							
Engelwood Cliffs, N. J.	2,570.3	44,500					
(S. B. Penick & Co. Div.							
New York, N. Y.)							
[illegible]hurst, N. J.				X	X	X	X
Montville, N. J.				X	X	X	
Newark, N. J.				X	X	X	
The Greyhound Corp.							
Phoenix, Ariz.	3,725						
(Armour Pharma. Co.							
Subs. Phoenix, Ariz.)							
Reheis Chemical Co					X	X	
Berkeley Hts. N. J.							
Kankakee, Ill.				X	X	X	X
Hexagon Laboratories, Inc.							
Bronx, N. Y.					X	X	
Hoffman-LaRoche, Inc.							
Nutley, N. J.							
Belvidere, N. J.					X	X	
Nutley, N. J.				X	X	X	X

FIGURE III -2d

PROFILE OF 45 MAJOR PHARMACEUTICAL COMPANIES

Company	Annual Sales 1975 $MM	No. of Empl.	Facility Profile (Based on Product Slate) A	B	C	D	E
Burdick & Jackson Labs Inc. Subs. Muskegon, Mich.							
ICI United States Inc. Wilmington, Del. (Stuart Pharma. Div. Wilmington, Del.)							
Newark, Del.					X	X	
Pasadena, Calif.					X	X	X
Inolex Corp. (American Can Co.) Chicago, Ill.	2,900	47,400					
(Inolex Pharma. Div. Chicago, Ill.)				X	X	X	X
International Rectifier Corp. El Segundo, Calif.	68	2,900			X	X	X
(Rachelle Labs. Inc. Long Beach, Calif.)							
Johnson & Johnson New Brunswick, N. J.	2,200	54,300			X	X	X
Johnson & Johnson New Brunswick, N. J.					X	X	X
J&J Baby Products Piscataway, N. J						X	X
Ethicon Somerville, N. J.					X	X	X
Ortho Pharma. Corp. Raritan, N. J.						X	X
Ortho Diagnostics Raritan, N. J.				X		X	X
McNeil Labs. Fort Washington, Pa.					X	X	X
Pitman-Moore, Inc. Washington Crossing, N. J.						X	X

FIGURE III -2e

PROFILE OF 45 MAJOR PHARMACEUTICAL COMPANIES

Company	Annual Sales 1975 $MM	No. of Empl.	Facility Profile (Based on Product Slate)				
			A	B	C	D	E
J & J/D. O. C. Gurabo, P. Rico						X	
Hemispherica S. Juan, P. Rico						X	
Ortho Pharma. P. Rico						X	
Eli Lilly & Co. Indianapolis, Ind	1,250	24,700					
Tippecanoe Labs. Lafayette, Ind.			X		X	X	X
Clinton Labs. Clinton, Ind.			X		X	X	
Mayaguez, P. Rico					X	X	
Mallinckrodt Inc. St. Louis, Missouri (Medicinal Div.)	240	3,700					
Jersey City, N. J.					X	X	
St. Louis, Missouri					X	X	X
Pharma. Prod. Div. Decatur, Ill.					X	X	X
Medical Chemical Corp. Santa Monica, Calif.						X	X
Medi-Chem, Inc. Santa Monica, Calif.						X	X
Merck & Co. Rahway, N. J. (Chemical Div)	1,490	27,000					
Albany, Geo.					X	X	X
Danville, Pa.			X	X	X	X	X
Elkton, Va.					X	X	X
Hawthorn, N. J.					X	X	
Rahway, N. J.				X	X	X	X

FIGURE III -2f

PROFILE OF 45 MAJOR PHARMACEUTICAL COMPANIES

Company	Annual Sales 1975 $MM	No. of Empl.	Facility Profile (Based on Product Slate) A	B	C	D	E
St. Louis, Mo.					X	X	
South San Francisco, Ca.					X	X	
(MSD Mfg. Div.)							
West Pt., Pa				X	X	X	X
MSD Quimica de P. Rico Inc. Subs.					X	X	X
Miles Laboratories							
Elkart, Ind	414	8,651					
(Marshall Div.)							
Clifton, N. J.					X	X	X
Elkart, Ind.					X		
Madison, Wis.					X	X	X
(Sumner Div.)							
Zeeland, Mich.					X	X	
Dome Labs. West Haven, Conn					X	X	
Minnesota Mining & Mfg.							
St. Paul, Minn.	3,100	83,609					
Riker Labs. Subs. Northridge, Calif.				X	X	X	X
Morton Norwich Products Inc.							
Chicago, Ill.	540	12,300					
Norwich Pharma. Co Norwich, N.Y.					X	X	X
Eaton Labs.							
Novo Enzyme Corp.							
Mamaroneck, N. Y.					X	X	X
Pfanstiehl Labs. Inc.							
Wankegan, Ill.					X	X	X

FIGURE III -2g

PROFILE OF 45 MAJOR PHARMACEUTICAL COMPANIES

Company	Annual Sales 1975 $MM	No. of Empl.	Facility Profile (Based on Product Slate) A	B	C	D	E
Pfizer, Inc.							
New York, N. Y.	1,665.5	39,500					
Brooklyn, N. Y.					X	X	X
Greensboro, N. C.					X		
Groton, Conn.					X	X	X
Terse Haute, Ind.					X	X	X
Milwaukee, Wis.					X	X	X
Pharmachem Corp.							
Bethlehem, Pa.					X	X	X
P-L Biochemicals, Inc.							
Milwaukee, Wis.					X	X	X
Polychemical Labs, Inc.							
Bronx, N. Y.				X	X		X
Richardson Merrell, Inc.							
Wilton, Conn.	658.7	15,000					
Lakeside Labs Div. Milwaukee, Wis.					X	X	X
J. T. Baker Chemical Co. Phillipsburg, N. J.					X	X	X
Merrell Natl. Labs. Cincinnati, Ohio					X	X	X
Vicks-Merrell Cayey, P. Rico					X	X	
Merrell-Natl. Labs. Swiftwater, Pa.					X	X	X
A. H. Robins Co.							
Richmond, Va.	240	4,500			X	X	X
Rhodia, Inc.							
New York, N. Y.							
New Brunswick, N. J.					X	X	X

FIGURE III -2h

PROFILE OF 45 MAJOR PHARMACEUTICAL COMPANIES

Company	Annual Sales 1975 $MM	No. of Empl.	Facility Profile (Based on Product Slate)				
			A	B	C	D	E
Schering-Plough Corp. Kenilworth, N. J.	800	15,600					
Kenilworth, N. J.					X	X	X
Union, N. J.				X	X	X	X
P. Rico							
G. D. Searle Co. Chicago, Ill.	720	18,700					
Skokie, Ill					X	X	X
Arlington Hts. Ill.					X	X	X
Puerto Rico							
Smithkline Corp. Philadelphia, Pa	589	13,225					
Philadelphia				X	X	X	X
Swedeland, Pa.				X	X	X	X
Puerto Rico						X	
Squibb Corp. New York, N. Y.	1,125	34,000					
New Brunswick, N. J.				X	X	X	X
Humacao, P. Rico					X	X	X
Sterling Drug, Inc. New York, N. Y.	960	27,376					
Glenbrook, Conn.					X	X	
Gulfport, Miss					X	X	
Trenton, N. J.					X	X	
(The Hilton-Davis Chem. Co. Div.) Cincinnati, Ohio					X	X	X
(Thomasset Color Div.) Newark, N. J.					X	X	

FIGURE III -2i 12/6/76

PROFILE OF 45 MAJOR PHARMACEUTICAL COMPANIES

Company	Annual Sales 1975 $MM	No. of Empl.	Facility Profile (Based on Product Slate)				
			A	B	C	D	E
(Winthrop Lab Div. New York, N. Y.)							
Reusselaer, N. Y.					X	X	X
Syntex Corp.							
Palo Alto, Calif.	250	6,150					
(Arapahoe Chemicals Div)							
Boulder, Colo.					X	X	X
Newport, Tenn.					X	X	X
(Syntex Agribusiness Inc)							
Springfield, Mo.					X	X	X
Verona, Mo.					X	X	X
Cutter Labs.							
Berkeley, Calif.				X	X	X	X
The Upjohn Co.							
Kalamazoo, Mich.	890	16,550					
Arecibo, P. Rico					X	X	X
Kalamazoo, Mich				X	X	X	X
Vitamins Inc.							
Chicago, Ill.					X	X	X
Warner-Lambert Co.							
Morris Plains, N. J.	2,100	58,500					
Nepera Chemical Co. Inc.					X	X	X
Harriman, N. Y.							
Park Davis & Co.				X	X	X	X
Holland, Mich							
Detroit, Mich				X	X	X	X
Warner-Chilcott Labs					X	X	X
Morris Plains, N. J.							

FIGURE III -2j

PROFILE OF 45 MAJOR PHARMACEUTICAL COMPANIES

Company	Annual Sales 1975 $MM	No. of Empl.	Facility Profile (Based on Product Slate)				
			A	B	C	D	E
Warner-Chilcott P. Rico					X	X	
Park Davis Plant Carolina, P. Rico					X	X	
Worthington Biochemical Corp.	8	210					
Freehold, N. J.				X	X	X	X

Source: 1975 Directory of Chemical Producers Stanford Research Institute

$ Sales and total no. of employees information derived from "Standard & Poors Corp."

United States. Most pharmaceutical manufacturing firms are located in New York, New Jersey, Pennsylvania, Indiana, Illinois, Michigan, Missouri, Ohio, and California, with production concentrated in the industrial areas of the East and the Midwest. In addition, there are approximately 60 pharmaceutical plants on the island of Puerto Rico. All but one of the plants surveyed for this study were located in one of these three high-production geographical areas.

The Pharmaceutical Manufacturers Association (PMA) estimates that there are between 600 and 700 firms in the United States producing prescription products. PMA represents 110 manufacturers who annually produce approximately 95 percent of the prescription products sold in the United States and an estimated 50 percent of total free-world output. Industry-wide market share data compiled by PMA show that 20 firms account for 75 percent of total sales in the United States. Five of the nine firms (16 plants) surveyed for this study are among these top 20. Figures III-2a--III-2j present a profile of 45 major pharmaceutical companies.

It should be noted that 71 establishments primarily engaged in production of commodities listed under codes SIC 2831, 2833 and 2834 have applied for NPDES discharge applications. Of these 71, twenty-three plants are designated as major dischargers. Forty-four plants were operating under NPDES permits as of September 1, 1976; thirteen permit applications are still active and one permit is being appealed (See Table III-4). Another 13 plants, including one major discharger, have withdrawn their applications since they are converting to municipal waste treatment systems. The status of NPDES discharge applications are listed in Tables III-4 and III-5.

A total of 23 plants were surveyed, of which ten are considered major dischargers. The distribution of plants surveyed by subcategory is as follows:

Subcategory	Number of plants
A	13
B	5
C	13
D	8
E	6

It should be noted that some pharmaceutical plants have processes in more than one subcategory. Where possible in such cases, the wastewater streams from the different

TABLE III-4

NUMBER OF DIRECT DISCHARGERS BY EPA REGION

DERIVED FROM ACTIVE NPDES PERMITS AND PERMIT APPLICATIONS

EPA Region	No. of Dischargers	Status
I	3	3 Active Permits
II	23	13 Active Permits; 10 Applications; 1 Deleted
III	8	7 Active Permits; 1 Issued & Appealed
IV	11	10 Active Permits; 1 Application
V	6	6 Active Permits; 10 No Permits Required
VI	2	2 Applications
VII	3	3 Active Permits; 2 Exempted
VIII	0	
IX	1	1 Active Permit
X	1	1 Active Permits
Total	58	44 Active Permits; 13 Active Applications; 1 Issued & Appealed; 13 Applications Withdrawn

TABLE III-5

NPDES PERMIT STATUS OF DIRECT DISCHARGER PHARMACEUTICAL MANUFACTURERS

EPA Region	NPDES Permit No.	Permit Status	Expiration Date	Facility & Location
I	ME0000400	Active	4-30-79	Marine Colloids, Inc., Rockland, ME.
	ME0000671	Active	4-30-79	Stauffer Chemical Co., South Portland, ME.
	ME0002585	Active	6-30-79	Morton Norwich Products, Winslow, ME.
II	NY0006335	Applied for		Diagnostic Research Inc., Roslyn, NY.
	NJ0000540	Active	6-29-80	Ciba-Geigy Corp., Summit, NJ.
	NJ0002585	Active	7-31-81	S.B. Penick Co. CPC Intl., Montville, NJ.
	NJ0002801	Applied for		Diamond Shamrock Corp. Nopco., Harrison, NJ.
	NJ0003671	Applied for		Merck & Co. Inc. Branchburg Farm, N. Branch
	NJ0004952	Active	7-31-79	Hoffmann-LaRoche Inc., Belvidere, NJ.
	NY0004243	Applied for		Kraftco Sheffield Chem Norwich, Norwich, NY.
	NY0004260	Active	6-30-77	Kraftco Sheffield Chem Oneonta, Oneonta, NY.
	NY0006670	Applied for		Nepera Chemical Co. Inc., Harriman, NY.
	PR0021148	Active	1-31-80	Merck Sharp & Dohme, Barceloneta, PR.
	PR0000353	Active	1-31-80	Eli Lilly & Co. Inc, Mayaguez, PR.
	PR0000540	Active	8-31-81	Warner Chilcott Labs, Carolina, PR.
	NJ0002542	Active	7-31-80	Warner Chilcott Labs, Morris Plains Boro, NJ.
	NJ0003905	Active	4-30-79	E.R. Squibb & Sons Inc., Hillsboro, NJ.
	NJ0005711	Active	9-30-80	Schering Corp., Lafayette, NJ.
	NY0004600	Applied for		Lederle Lab Div. Amer. Cyan., Pearl River, NY.
	NY0006408	Applied for		General Mills Chemicals Inc., Ossining, NY.
	PR0000124	Deleted		Lederle Diagnostics de Puerto, Carolina, PR.
	PR0000361	Active	12-31-79	Eli Lilly & Co. Inc., Carolina, PR.
	PR0000388	Applied for		Brischem Inc., Barceloneta, PR.
	PR0001104	Active	1-31-80	Manufacturing Enterprises Inc., Humacao, PR.
	NJ0027618	Applied for		E.R. Squibb & Son Inc., Princeton, NJ.
	NY0033219	Applied for		USV Pharmaceutical Corp., Tuckahoe, NY.
	NY0004146	Active	12-31-79	Morton Norwich Products, Norwich, NY.
III	DE0000060	Active	9-10-76	Barcroft Co., Lewes, DE.
	PA0008419	Active		Merck & Co. Inc. Cherokee Plant, Riverside, PA.
	VA0002178	Issued & Appealed		Merck & Co. Inc. Stonewall Plant, Elkton, VA.
	PA0002891	Active		West Agro. Chem. Eighty Four Pt., N. Strab. Twp.
	PA0012696	Active		McNeil Lab Inc. Ft. Wash., Whitemarsh Twp., PA.
	VA0003042	Active		Puremade Products, Hopewell, VA.
	MD0022560	Active		Abbott Labs Agri.& Vl. Worchester Co. Sd.,MD.
	PA0028118	Active		National Milling & Chem. Co., Philadelphia,PA.
IV	GA0001619	Active	6-30-79	Merck & Co. Flint Rv. Plt. Albany, Putney, GA.
	NC0003263	Active	2-13-80	Mallinckrodt Chem Raleigh, Wake County, NC.
	TN0001481	Active	2-13-79	Cutter Labs Inc., Chattanooga, TN.
	MS0000833	Active	6-30-79	Travenol Lab Cleveland, Bolivar County, MS.
	NC0001589	Active	8-11-80	Abbott Lab Rocky Mount, Nash County, NC.
	NC0003506	Active	1-31-80	R.J. Reynolds Tobacco, Win. Salem, Merry Hill
	NC0006564	Active	11-15-78	Travenol Lab North Cove, McDowell County, NC.
	SC0003123	Active	7-25-80	Travenol Lab Kingstree, Kingstree, SC.
	TN0002780	Active	6-1-79	Chattem Drug & Chem., Chattanooga, TN.
	MS0027995	Active	12-31-79	Vicksburg Chemical Co., Vicksburg, MS.
	NC0027928	Applied for		Vick. Mfg. Divn. Richardson Me., Greensboro
V	IN0001104	Active	1-31-79	Dow Chemical-Human Health R & D, IN.
	IN0001112	No Permit Required		Dow Chemical Co. - Biological Lab.
	MI0000922	No Permit Required		Parke Davis & Company.
	MI0001945	No Permit Required		Parke Davis & Company, Detroit, MI.
	MI0025330	No Permit Required		Parke Davis & Co.-Parkedale Bio. Avon Twp., MI.
	IL0002003	No Permit Required		Alba Mfg. Co. - NPR, IL.
	IN0002852	Active		Eli Lilly & Co. Clinton Labs, Clinton Twp., IN.
	IN0002861	Active		Eli Lilly & Co., Lafayette, IN.
	IN0003581	No Permit Required		Pfizer Inc., Terre Haute, IN.
	MI0004715	Active		Park, Davis, & Co-Holland Chem, Holland, MI.
	IL0001881	No Permit Required		Abbott Labs., North Chicago, IL.
	IL0002445	No Permit Required		Sterling Drug Inc. -- Glenbrook, IL.
	IL0003191	No Permit Required		Pierce Chemical Co., IL.
	IL0024074	Active		Travenol Labs Inc., Round Lane Sd., IL.
	IL0038831	No Permit Required		Mallinckrodt Chem. WKS-NPR, IL.
	MI0027235	Active		Ash Stevens Inc., MI.
VI	AR0001783	Applied for		Travenol Labs-Baxter, Mountain Home, AR.
	TX0064912	Applied for		Hoffmann-LaRoche, Freeport, TX.
VII	NE0111091	Exempt		Armour-Baldwin Labs., Omaha, NE.
	NE0000701	Active	10-13-77	Dorsey Labs, Lincoln, NE.
	NE0111295	Exempt		Pfizer Inc., Sidney, NE.
	MO0001970	Active	6-8-80	Syntex Agribusiness, Inc., Springfield, MO.
	MO0001716	Active	9-25-79	Amer. Cyanamid Co., Hannibal, MO.
IX	CA0002526	Active	11-30-76	McGaw Labs, Glendale, CA.
X	WA0021539	Active	2-15-80	I. P. Callison & Son, Chehalis, WA.

processes were examined separately and are considered as separate plants for the purpose of the above accounting.

From this, it is concluded that the data base has statistical validity and that it is adequate for the type of logic stream used in this report.

Units of Expression

Units of pharmaceutical production are shown in kilo-kilograms (kkg) which is the same as 1000 kilograms or a metric ton. In-plant liquid flows are sometimes shown in cubic meters per day (cu m/day) and treatment plant capacities are shown as gallons per day (gpd) or as millions of gallons per day (mgd).

Metric units may be converted to English units by using the following factors:

1 cubic meter (cu m) = 1 kL = 264.2 gallons
1 kilogram (kg) = 2.205 pounds (lbs)
1 kilo-kilogram (kkg) = 2205 pounds = 1 metric ton
1 kg/kkg = 1 kilogram of substance per kilo-kilogram of product = 1 pound of substance per 1000 pounds of product
1 milligram per liter (mg/1) = 1 part per million (ppm) = 8.34 lbs/million gal water or 1 g/cu m water.

For other metric unit to English unit conversions, see Table XVIII.

SECTION IV

INDUSTRIAL CATEGORIZATION

General

The purpose of this study is the development of effluent limitations and guidelines for the pharmaceutical manufacturing point source category that will be commensurate with different levels of in-process waste reduction and end-of-pipe pollution control technology. These effluent limitations and guidelines are to specify the quantity of pollutants which will ultimately be discharged from a specific facility. Recognizing that the industries considered in the total study of the miscellaneous chemicals category (pharmaceuticals, gum and wood, pesticides and agricultural chemicals, adhesive and sealants, explosives, carbon black and photographic processing) are quite diverse in raw materials, manufacturing processes, products and wastewaters, each major industry is treated independently as a category. Specific subcategories are explained in this development document for the pharmaceutical manufacturing point source category.

Pharmaceutical Manufacturing

Discussion of the Rationale of Subcategorization

Subcategories are established for the pharmaceutical manufacturing point source category to define those segments of the industry where separate effluent limitations and standards should apply. Subcategorization is based on production methods and the wastewaters generated. These subcategories are:

A. Fermentation Products
B. Extraction Products
C. Chemical Synthesis Products
D. Mixing/Compounding and Formulation
E. Research

The underlying distinctions between the various subcategories have been based on the wastewater generated, its quantity, characteristics and applicability of control and treatment. The following factors have been considered in determining whether such subcategorizations are justified:

Manufacturing Processes

There are six basic processing techniques in common use in the pharmaceutical manufacturing industry. These techniques, all distinctly different, are: fermentation, chemical synthesis, formulation, fractionation, natural extraction and the growth and isolation of cultures. The first three of these techniques are by far the most widely used.

Fermentation processes are used extensively in the pharmaceutical manufacturing point source category to produce antibiotics. Fermentation plants are large water users and the basic process steps used at these facilities are similar throughout the industry. The basic production steps consist of the initial fermentation step, a separation step (usually vacuum filtration or centrifugation) and finally a series of extraction and purification steps. The major wastewater from this processing technique is spent beers from the initial fermentation step.

Chemical synthesis is another major production process in pharmaceutical manufacturing. Hundreds of different products are made each year using chemical synthesis techniques, which include alkylations, carboxylation, esterification, halogenation, sulfonation, etc. Chemical synthesis plants are also large water users.

The third major production process in pharmaceutical manufacturing is formulation. Formulation plants receive bulk chemical and fermentation products as raw materials and subsequently manufacture the final dosage forms (tablets, liquids, capsules, etc.). Some of the unit operations utilized for formulating final products include drying, blending, grinding, grading, mixing, labeling, packaging, etc. Compared to the fermentation and chemical synthesis processes, formulation is a relatively small water user.

Fractionation, natural extraction and biological culture growth and separation processing techniques are used on much smaller production scales than the three previously discussed techniques. Fractionation techniques consist of a series of centrifugation and chemical extraction steps. Natural extraction techniques use animal and plant tissues as product raw materials and also consist of various separation and chemical extraction steps. Biological cultures are another raw material of medicinal products. Cultures are grown under optimum conditions and then go through a series of seeding, isolation, incubation and drying steps. These three processing techniques are generally conducted in laboratories on a bench-top scale and therefore are very small water users.

It was concluded that the nature of the manufacturing process in the pharmaceutical manufacturing point source category formed a basis for subcategorization.

Product

Under the Standard Industrial Classification coding system, the pharmaceutical manufacturing industry is divided into three product areas: Biological Products (SIC 2831), Medicinal Chemicals and Botanical Products (SIC 2833) and Pharmaceutical Preparations (SIC 2834). Within the Medicinal Chemicals and Botanical Products classification, there are three additional major product areas: fermentation products, chemical synthesis products and natural extraction products. Fermentation products are primarily steroids and antibiotics. Chemical synthesis products include intermediates used to produce other chemical compounds as well as hundreds of fine chemical products. These chemicals are used to ultimately produce the gamut of medicinal products. Biological products include vaccines, serums and various plasma derivatives. Natural extractions include such items as animal gland derivatives, animal bile salts and derivatives and herb tissue derivatives. Formulation products are manufactured from the end products of the other manufacturing areas and include the merchandise which is finally marketed to the public.

It was concluded that the nature of the product manufactured by the pharmaceutical manufacturing point source category formed a basis for subcategorization.

Raw Materials

The pharmaceutical manufacturing industry draws upon worldwide sources for the myriad of raw materials it needs to produce medicinal chemicals. Fermentation plants require many raw materials falling into general chemical classifications such as carbohydrates, carbonates, steep liquors, nitrogen and phosphorus compounds, anti-foam agents and various acids and bases. These chemicals are used as carbon sources, as nutrient sources, for foam control and for pH adjustment in fermentation processes. Various solvents, acids and bases are also required for extraction and purification processes. Hundreds of raw materials are required for the many batch chemical synthesis processes used by the pharmaceutical manufacturing point source category. These include organic and inorganic compounds and are used in gas, liquid and solid forms.

Plant and animal tissues are also used by the pharmaceutical manufacturing industry to produce various biological and natural extraction products. The raw materials used by pharmaceutical formulation plants are the products of the other manufacturing areas. These include bulk chemicals from fermentation and chemical synthesis plants as well as such items as biles, blood fractions, salts and various derivatives from biological and natural extraction facilities.

It was concluded that the nature of raw materials used by the pharmaceutical manufacturing point source category formed a basis for subcategorization.

<u>Plant Size</u>

From inspection of historical and plant visit data, it was determined that plant size, measured in terms of production, apparently has no significant effect on the pounds of pollutant per pound of production (RWL).

Plant size, measured in terms of total gross floor area, could be used as the basis for computing raw waste loads for the plants in subcategory E. This proved to be a consistent yardstick for this subcategory in lieu of any production that can be quantified.

<u>Plant Age</u>

During the study, old and new plants within each subcategory were visited. Following the analysis of actual survey and historical data, it was concluded that plant age is not a significant factor in determining the characteristics of a plant's wastewater. Both the presence and absence of separate sewer systems for sanitary and process wastewaters have been observed in both old and new plants. The age of a plant is related more to the location of the plant than to the quantity or characteristics of the plant's wastewaters. The older plants are located in urban areas, whereas the newer plants are sited in rural areas. This will affect the cost of treatment facilities because of land costs and land availability.

<u>Plant Location</u>

From inspection and wastewater sampling of plants located in three geographical areas of the country and from analysis of existing data, it is concluded that plant location does not affect the quality or quantity of the process wastewater streams. The geographical areas surveyed included the

Midwest, the Northeast, the Middle Atlantic States and the Southeast (Puerto Rico). Geographical location did affect the management of non-process streams such as non-contact cooling water. Recirculation of cooling water was more common in the warm climate areas (where water conservation was of more concern) than in temperate geographical regions.

Housekeeping

Plant housekeeping was another factor considered when comparing the various plants visited during the study. The pharmaceutical industry has been under a form of pollution control for a number of years. Certain control standards for cleanliness, sanitation, hygiene and process control are matters of particular importance to the industry because of its concern about product quality. As a result of these considerations, the pharmaceutical manufacturing point source category has, as a matter of course, practiced unusually good manufacturing and housekeeping procedures as they apply to both processes and personnel. In addition, the pharmaceutical industry has for years been subject to certain manufacturing and operational restrictions and inspections pertaining to the regulations of the Federal Food, Drug and Cosmetic Act. Periodically, FDA personnel will call on a pharmaceutical manufacturer for an unannounced in-plant inspection covering plant housekeeping practices. Good manufacturing practices regulations promulgated by the FDA have been in force, with modifications, since 1963. In addition, since the chemical costs to produce pharmaceutical products are high, inventories are closely watched and checked, inadvertent spills and batch discharges are closely monitored and housekeeping practices are maintained at the optimum. Due to the strict regulations concerning cleanliness enforced by the FDA, the housekeeping practices observed at all the plants visited were exceptionally good and therefore they were not a factor in affecting wastewater quantities and characteristics. Also, except for the nuclear industry in certain cases, as a rule the pharmaceutical industry places greater emphasis upon the purity of its products than does any other industry.

Air Pollution Control Equipment

The type of air pollution equipment employed by a facility can affect the characteristics and the quantity of the process wastewater streams. The use of both dry and wet pollution control equipment was observed in several areas of the pharmaceutical manufacturing industry. However, these wet devices can produce a larger quantity of process wastewaters than dry air pollution control equipment.

Nature of Wastes Generated

Various pharmaceutical manufacturing processes have been examined for the types of contact process water usage associated with each. Contact process water is defined as all water which comes in contact with chemicals (including pharmaceutical products) within the pharmaceutical manufacturing process and includes:

1. Water required or produced (in stoichiometric quantities) in a chemical reaction.

2. Water used as a solvent or as an aqueous medium for the reactions.

3. Water which enters the process with any of the reactants or which is used as a diluent (including steam).

4. Water used as an absorbent or scrubbing medium for separating certain chemicals from the reaction mixture.

5. Water introduced as steam for stripping certain chemicals from the reaction mixture.

6. Water used to wash, remove, or separate chemicals from the reaction mixture.

7. Water associated with mechanical devices such as steam-jet ejectors for drawing a vacuum on the process and vacuum pumps.

8. Water used as a quench (including ice) or direct contact coolant, such as in a barometric condenser.

9. Water used to clean or purge equipment used in batch-type operations.

The type and quantity of contact process water usage are related to the specific unit operations and chemical conversions within a process. The term "unit operations" is defined to mean specific manufacturing steps, such as fermentation, distillation, solvent extraction, crystallization, purification, chemical synthesis, absorption, etc. The term "chemical conversion" is defined to mean specific reactions, such as oxidation, halogenation, alkylation, esterification, etc.

Although the study survey teams were not allowed to sample individual unit operations, it could be seen from evaluation of all available data that the characteristics of the wastewaters generated by the different manufacturing techniques utilized by the pharmaceutical manufacturing industry varied considerably. The wastewaters from fermentation processes consisted of high strength spent fermentation beers, equipment washwaters, floor washwaters and waste solvents. The many batch operations used in chemical synthesis operations were a cause of highly variable wastewaters containing many constitutents. The wastewater flows from formulation operations are almost exclusively equipment and floor washwaters.

Biological, natural extraction and research facilities generate much less wastewater than the other manufacturing processes. Their wastewater flows are intermittent and animal wastes are often found in the effluents from research buildings.

It was concluded that the nature of the wastewaters generated by the pharmaceutical manufacturing point source category formed a basis for subcategorization.

Treatability of Wastewaters

The pollutant loading from plants within the different manufacturing areas varied widely and therefore the treatment technologies employed by companies throughout the industry varied from highly sophisticated thermal oxidation plants to small biological package plants.

The wastewaters generated by fermentation and chemical synthesis processes contain much higher pollutant concentrations than those generated from the manufacturing of biological and natural extraction products. Formulation plants generally discharge wastewaters with moderate strengths. The lowest strength wastes sampled were those attributed to research facilities. It was concluded that the treatability of the wastewaters generated by the pharmaceutical point source category formed a basis for subcategorization.

Summary of Considerations

It was concluded that, for the purpose of establishing effluent limitations guidelines and standards, the pharmaceutical manufacturing point source category should be grouped into five subcategories. This subcategorization was based on distinct differences in manufacturing processes, raw materials, products, and wastewater characteristics and treatability. The five subcategories that have been selected for the pharmaceutical manufacturing point source category are:

A. Fermentation Products
B. Extraction Products
C. Chemical Synthesis Products
D. Mixing/Compounding and Formulation
E. Research

Because large research animals are sometimes found in research facilities there is a potential subcategory E2 (Research Farm) for future consideration.

Description of Subcategories

Subcategory A - Fermentation Products

Fermentation is an important production process in pharmaceutical manufacturing. This is the basic method used for producing most antibiotics (penicillin, streptomycin, etc.) and many of the steroids (cortisone, etc.). The product is produced in batch fermentation tanks in the presence of a particular fungus or bacterium. The culture may be the product, or it may be filtered from the medium and marketed in cake or liquid form as animal feed supplement. The product is extracted from the culture medium through the use of solvents, activated carbon, etc. The antibiotic is then washed to remove residual impurities, concentrated, filtered and packaged.

The most troublesome waste of the fermentation process and the one most likely to be involved in water pollution problems, is spent beer. This is the fermented broth from which the valuable fraction, antibiotic or steroid, has been extracted. Spent beer contains a large amount of organic material, protein and other nutrients. Although spent beer frequently contains high amounts of nitrogen, phosphate and other plant nutrients, it is also likely to contain salts, such as sodium chloride and sodium sulfate, from the extraction processes.

This subcategory includes the unit operations which follow the fermentation steps that are used to separate the product from the fermentation broth. These include physical separation steps, such as vacuum filtration and centrifugation, as well as chemical separation via solvent extraction and distillation. Fermentation requires large quantities of water. The primary liquid wastes include the fermentation beers; inorganic solids, such as diatomaceous earth, which are utilized as a pre-coat or an aid to the filtration process; floor and equipment washings; chemical wastes such as solvents; and barometric condenser water from evaporation.

Subcategory B - Biological and Natural Extraction Products

Biological product manufacturers produce bacterial and virus vaccines, toxoids and analogous products (such as allergenic extracts), serums, plasmas and other blood derivatives for human or veterinary use. The primary manufacturing steps in blood fractionation include chemical precipitation, clarification, extraction and centrifugation. The primary wastewater sources are precipitates, supernatants, centrates, waste alcohols and tank washings. The precipitates and waste alcohols can be incinerated or reclaimed, while dilute wastes (supernatants, centrates and tank washings) are sewered. The production procedures for vaccines are generally lengthy and involve numerous batch operations. Unit operations include incubation, centrifugation, staining, freezing, drying, etc.

Liquid wastes associated with the process consist primarily of spent media broth, waste eggs, glassware and vessel washings, animal wastes, bad batches of production seed and/or final product and scrubber water from air pollution control equipment. Spent media broth, bad batches, waste eggs, animal carcasses and contaminated feces are normally incinerated. Wastes from small non-infected control animals may be landfilled. Equipment washings, animal cage washings and scrubber blowdowns are usually sewered.

Natural extractions manufacturing includes the processing (grading, grinding and milling) of bulk botanical drugs and herbs. Establishments primarily engaged in manufacturing agar and similar products of natural origin, endocrine products, manufacturing or isolating basic vitamins and isolating active medicinal principals such as alkaloids from botanical drugs and herbs are also included in this industry. The primary wastewater sources include floor washings, residues, equipment and vessel washwaters and spills. To the maximum extent possible, bad batches are corrected rather than discarded. When bad batches cannot be corrected, liquids are generally discharged to the plant sewer system. Solid wastes are usually landfilled or incinerated.

Subcategory C - Chemical Synthesis Products

The production of chemical synthesis products is very similar to fine chemicals production and uses the following major unit processes: reaction, extraction, concentration, separation, solvent recovery and drying. The synthesis reactions are generally batch types which are followed by extraction of the product. Extraction of the pharmaceutical product is often accomplished through solvents. The product may then be washed, concentrated, filtered and recrystallized to the desired purity and dried. The major wastewater sources include tank washes, equipment washes, spent cooling water and condenser discharges. These wastes are generally amenable to biological treatment.

Subcategory D - Mixing/Compounding and Formulation

Formulation operations for synthesis products may be either dry or wet. Dry production involves dry mixing, tableting or capsuling, and packaging. Process equipment is generally vacuum cleaned to remove dry solids and then is washed down. Scrubber blowdown from air pollution control devices may also be a wastewater source, and baghouses (for air pollution control) will generate a solid waste requiring disposal. Wet production involves mixing and blending in large vats and subsequent bottling and packaging. The primary wastewater sources include tank and equipment washings and spills.

Subcategory E - Microbiological, Biological and Chemical Research

Generally, quantities of materials being discharged by a research operation are relatively small when compared with the volumes generated by production facilities. However, the problem cannot be measured entirely by the volume of material going to the sewer. Research operations are frequently erratic as to quantity, quality and time schedule when dumping occurs. The most common problem is the disposal of flammable solvents (especially low-boiling-point solvents like ethyl ether), which can result in explosions and fires. The most effective approach to this problem is to require laboratory personnel to dispose of all waste solvents in special containers available in the laboratories and to have the material hauled away by a contractor. The effluent limitations for this subcategory were based on total gross floor area, since this proved to be a more consistent measure than production rate. This approach is logical, in lieu of any product that can be easily quantified.

Further study is being made of possible subclassification in recognition of excrement from large animals at certain research farms. These wastes resemble feedlot wastes, and their limitations might be based cn total animal weight or population equivalent.

Process Descriptions

The production from a given process is obviously related to the design capacities of the individual unit operations within it. In many cases the unit operations are arranged as a single train in series. In other cases, certain unit operations are arranged in parallel, as in an operation utilizing several small reactors simultaneously.

There are two major types of manufacturing process within the industry:

1. Continuous processing operations.
2. Batch processing operations.

Manufacturing processes can be classified in this manner by the flow of material between unit operations within a process, which may be either a continuous stream or a series of batch transfers. Both types of processes normally have an associated design capacity which is expressed in terms of thousands of pounds of product per year.

In large-scale continuous processes, all of the subsections of the process module are operated with the use of automated controls; in some cases, complete automation or computer control is utilized. Recording instruments maintain continuous records of process variables such as temperature, pressure, flow of fluids, viscosity, pH, liquid level and the composition of various process streams. Instrumentation for the indicating, recording and control of process variables is an outstanding characteristic of modern chemical manufacture. The function of the operators, mechanical technicians and supervising engineers in this type of operation is to maintain the process module in proper running order and to keep process parameters within desirable ranges. In large continuous operations, equipment is frequently segregated to the extent that each process module is located in its own building or plant location. In such operations, there is often complete segregation of contact process waters from non-contact cooling waters.

In general, the chemical processing area of a pharmaceutical manufacturing plant is made up of a number of batch reactors followed by intermediate product storage and purification steps, such as crystallization, distillation, filtration, centrifugation, solvent extraction and other unit operations either singularly or in combination. Since some equipment may be common to several product needs, careful equipment cleaning is necessary to avoid cross-contamination.

The washings flow to the drainage system and can thus be collected for subsequent treatment. Where a solvent is necessary in the cleaning steps for a vessel cleanout, the vessel is closed and cleaned by recirculation of the solvent through a pump system. The contaminated solvent is then discharged to a hold tank for purification by stripping and subsequent recovery drawoff. The tars or sludges are usually incinerated or hauled to a landfill. In some very small production facilities, the solvent may be disposed of to an approved disposal firm.

Where solvents are used for cleaning, plant safety becomes a primary concern. It is extremely important to minimize the discharge of water-insoluble solvents to plant drains, where a simple spark could create a major castastrophe. Plant safety is of constant concern and fire hazards are to be avoided as much as possible. Consequently, plant safety measures help eliminate gross discharges of such organics, although low concentrations remain in dissolved, dispersed, or emulsified form and require subsequent treatment.

Where solvents are used, both for process and vessel cleaning, most plants practice solvent recovery. A few plants also strip weak organic solutions to reduce contaminant loadings further. The stripping operation is carried to the point where the organic solution can safely be combined with other process wastes.

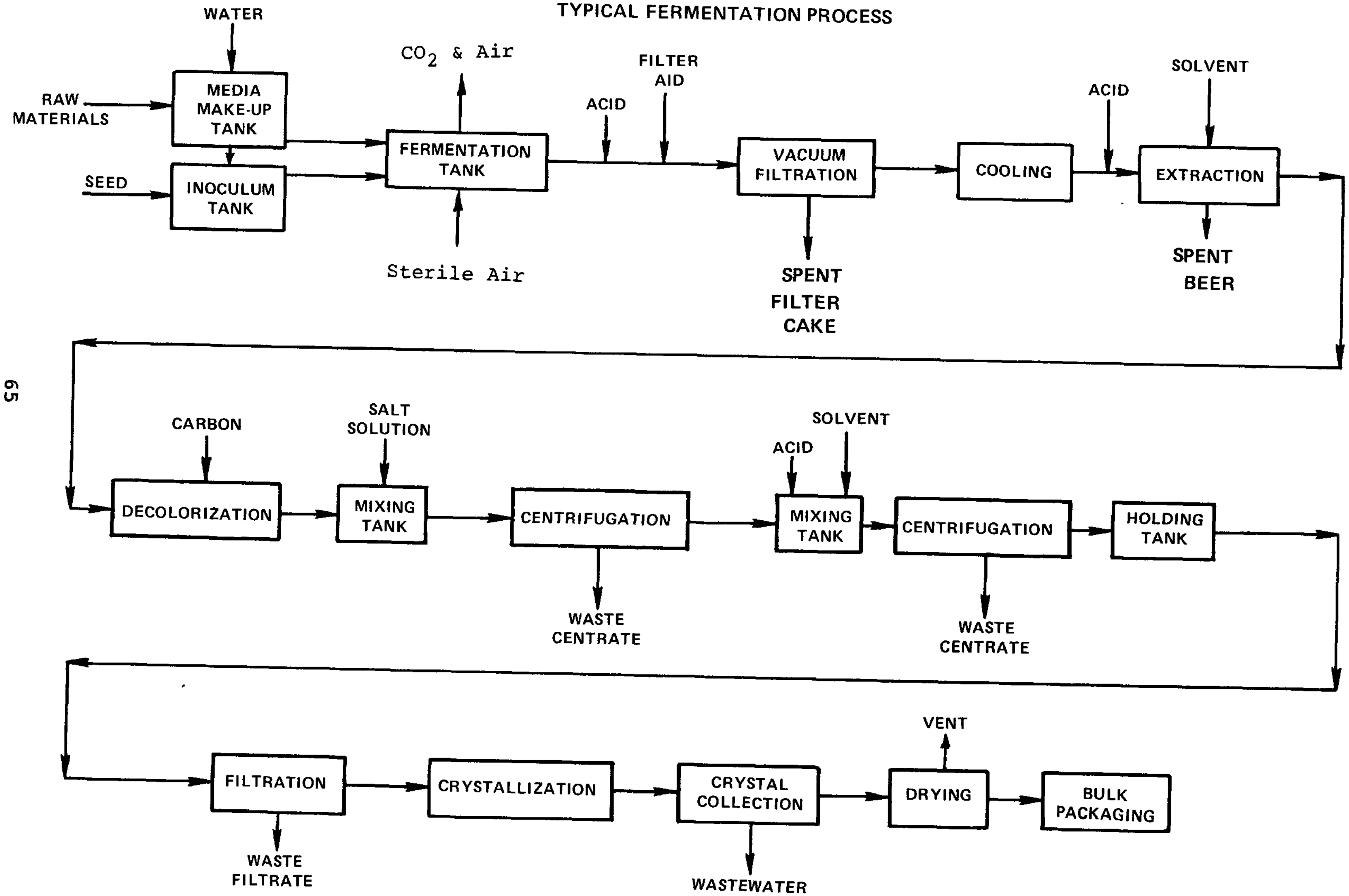
A number of the pharmaceutical manufacturing plants have evaporation and incineration units to aid in their disposal of specific organic wastes which might be difficult to treat biologically.

<u>Subcategory A - Fermentation Products</u>

Historically, the pharmaceutical manufacturing industry has used materials of plant and animal origin as sources for drugs. The industry also goes a step further and employs

FIGURE IV -1a

TYPICAL FERMENTATION PROCESS



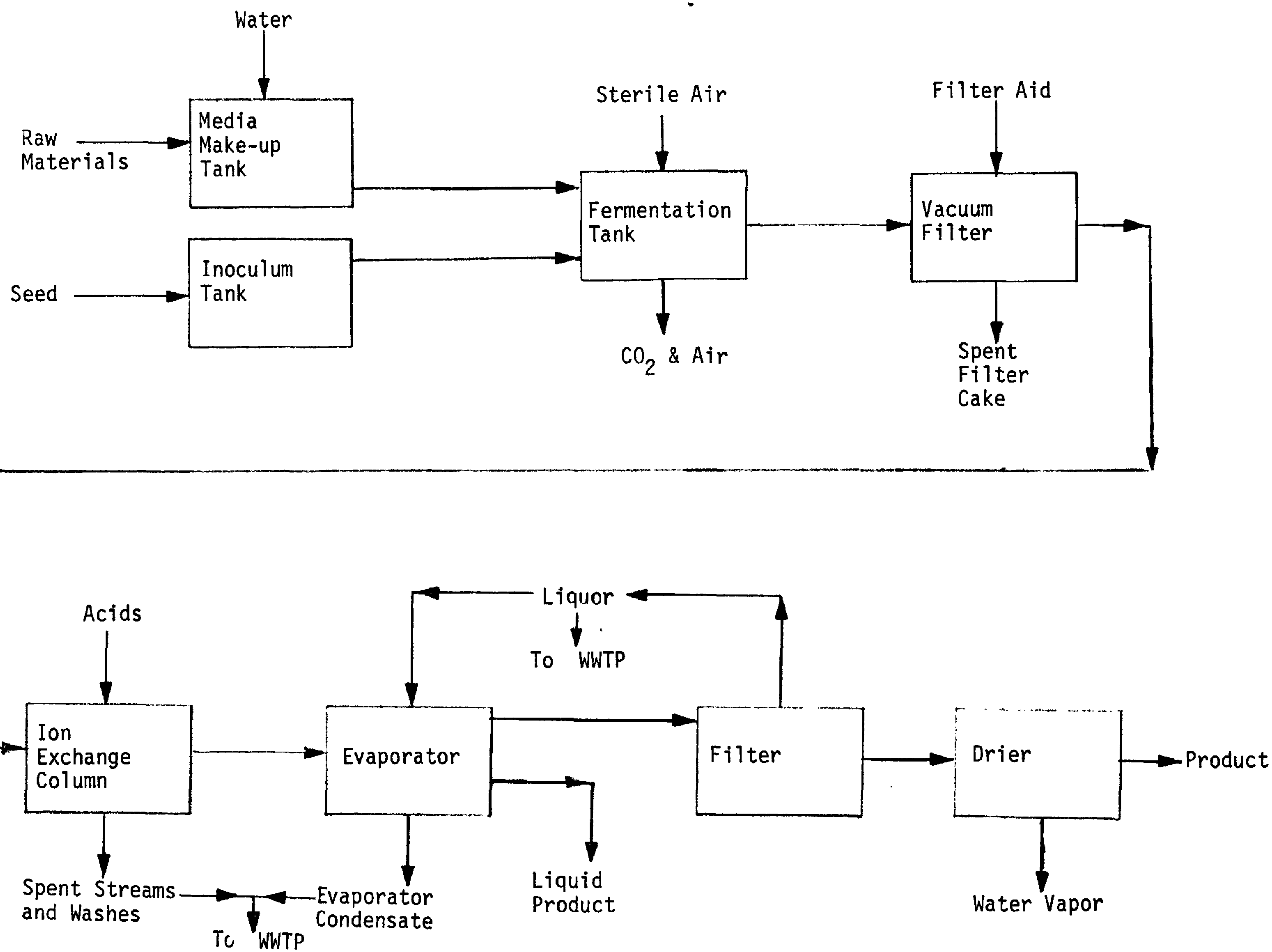
the life processes of plants and animals (especially from microorganisms) to produce useful medications. An excellent example of this is the fermentation process, in which microorganisms are permitted to grow under controlled conditions to produce valuable and often complex chemicals. With a few exceptions, notably chloramphenicol and cycloserine (which are produced by chemical synthesis), all antibiotics are produced by fermentation. The technique involves growing the microorganism on a large scale in totally enclosed tanks ranging in size from 5,000 to 25,000 gallons under conditions which force the microorganism to produce the maximum quantity of the antibiotic. Control of microorganism activity is achieved by the following techniques:

1. The culture is grown in a fermentation medium which contains the various ingredients required by the organism for its nutrition, e.g., a carbohydrate such as glucose, sucrose, lactose, or starch; a simple nitrogen source, such as urea or ammonium sulfate; or a more complex nitrogen source, such as soybean meal, cornsteep liquor, whey, cottonseed meal, or a meat digest. In addition, various salts may be added to provide the organism with its nutritional requirements for one or more of the cations (manganese, magnesium, copper, iron, potassium) and for one or more of the anions (phosphate, sulfate and chloride). Sometimes other materials such as oil or yeast extract are added. If the organism is aerobic, sterilized air is introduced through a sparger in the bottom of the vessel and dispersed throughout the fermenting broth by agitation. It should be emphasized that the fermentation medium is one which is devised to stimulate maximum antibiotic production and not necessarily meet the normal nutritional requirements of the organism.

2. The organism is grown under conditions of pure culture, i.e., in the absence of any competing microorganism. This is achieved by sterilizing the medium and the fermentor with heat, usually from steam; by aerating with sterile air, usually obtained by passage through a filter containing glass wool or carbon; and by preventing the entrance of foreign microorganisms during the fermentation period through operation of the vessel under positive pressure and the use of steam seals on all connecting lines.

FIGURE IV-1b

TYPICAL FERMENTATION PROCESS WITH ION EXCHANGE REFINING STEPS



3. Close control of the physical environment is achieved by continuous mixing of the batch to ensure intimate contact of the microorganism with the components of the medium; by control of the batch temperature; and finally by control of the pH. This latter control may be achieved either by relying on the metabolism of the organism combined with the proper balance of medium ingredients to give the desired pH pattern, or by the addition of acid or bases as needed. Aerated fermentations often foam excessively and, as a consequence, a defoamer is usually added intermittently to keep the batch under control.

   The choice of defoamer is influenced by its defoaming ability and its toxicity to the fermentation. Interference with product isolation in the refining step is another factor to be considered.

4. In a few isolated cases, product formation is stimulated by the addition, throughout the fermentation, of a compound which the organism can incorporate into the final product. An example of this occurs in the production of benzylpenicillin, when phenylacetic acid is added, to be incorporated into the benzyl side chain. Similarly, phenoxyacetic acid is used to stimulate the production of phenoxymethyl penicillin.

The antibiotic may be accumulated within the cells of the microorganism or excreted into the surrounding aqueous medium, or a combination of the two may occur. Usually, the antibiotic is recovered from the fermentation broth by utilizing techniques basically related to solvent extraction of the filtrate and/or cells such as selective ion exchange, chromatography, precipitation, or a combination of these.

In a number of fermentation operations, it is possible to recover the suspended mycelia and nutrients present in the spent beer. They can then be concentrated, dried and sold as an animal feed supplement. Of course, for these solids to be utilized in such a manner, the fermentation waste must be free of hazardous components. Landfilling is designated by some companies for such solids when reuse is not feasible.

Although many antibiotics are produced commercially, the general fermentation processes used are very similar. Flowcharts for typical fermentation processes are depicted

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FIGURE IV -2

TYPICAL FERMENTATION PROCESS

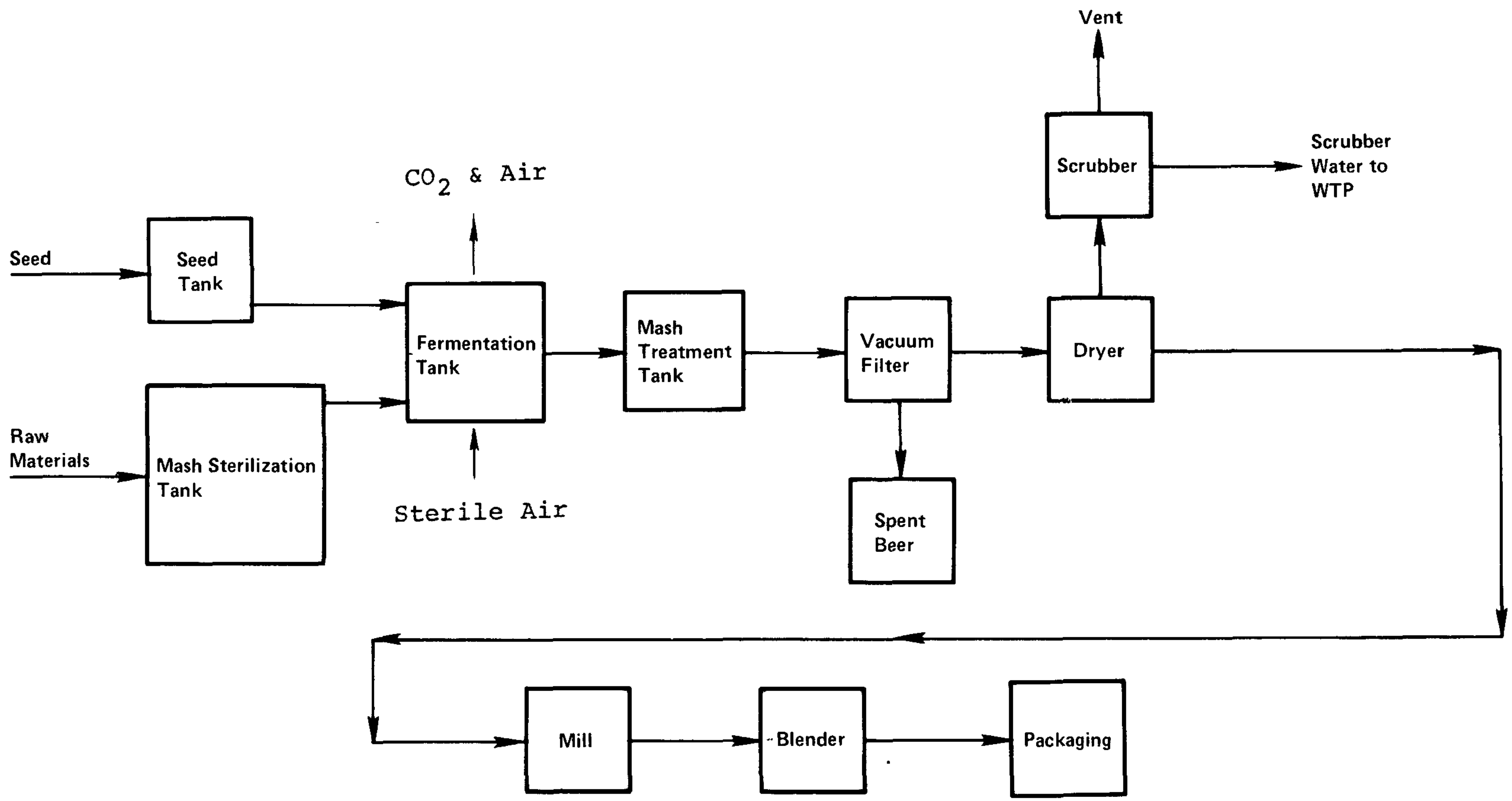
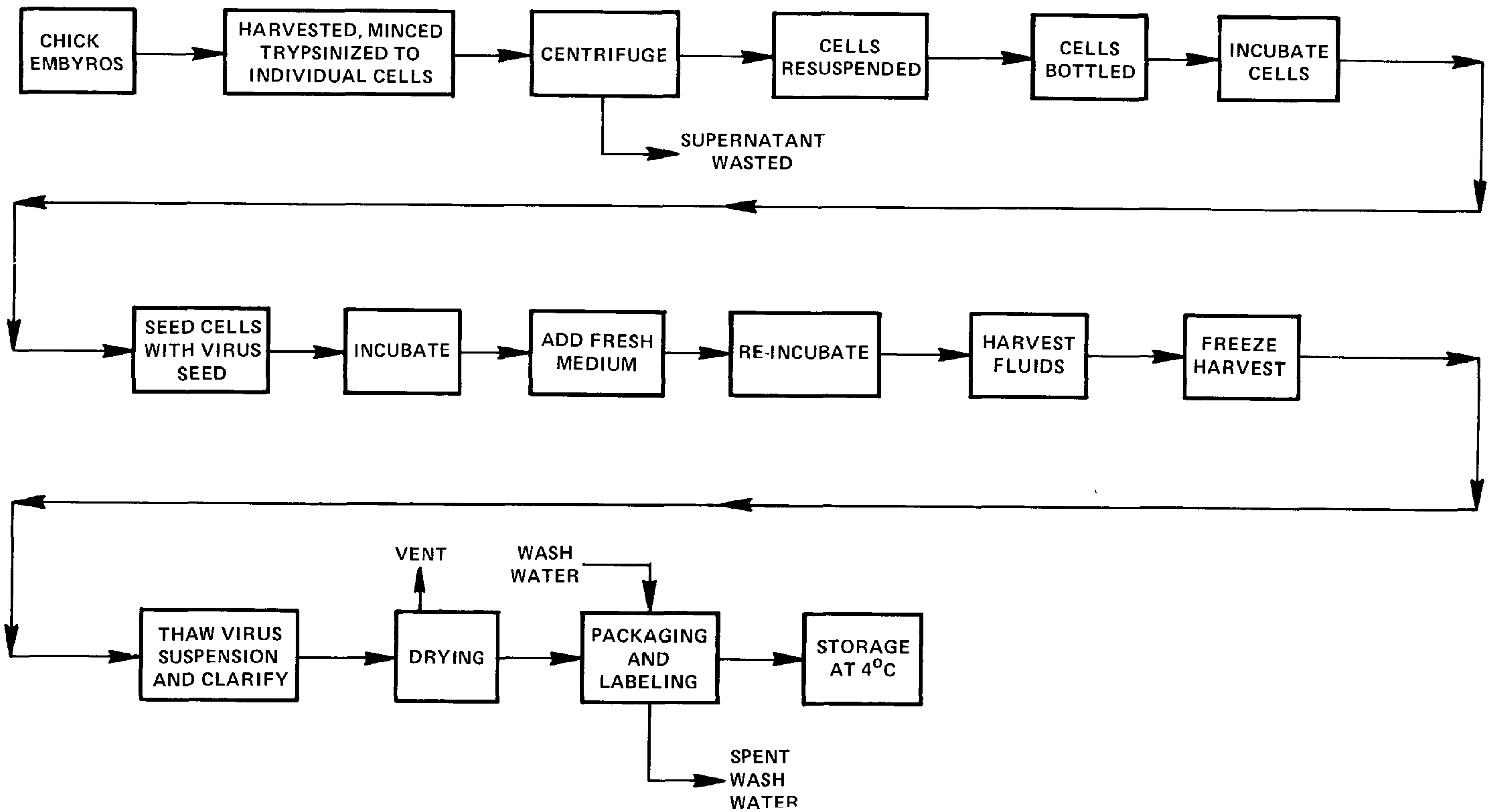


FIGURE IV -3

TYPICAL VACCINE PRODUCTION PROCESS



in Figures IV-1a, IV-1b and IV-2. The major wastewater sources are the spent beer from the fermentation step, equipment washdowns, floor washwaters and spent solvents from subsequent extraction steps.

<u>Subcategory B - Biological and Natural Extraction Products</u>

A biological product is any virus or bacterial vaccine, therapeutic serum, toxin, antitoxin, blood derivative, or analogous product applicable to the prevention, treatment, or cure of diseases or injuries in man. They are created by the action of microorganisms, and they are used for prophylaxis, treatment and diagnosis of infections and allergic diseases. Biological products are valuable for producing immunity to infections and preventing epidemics caused by contagious diseases. The two major production processes in this group are blood fractionation and vaccine production.

Numerous refinements of the detailed procedures for blood fractionation have been made to increase the yield and purity of the various components. The principal methods presently in use for large scale separations are called method 6, method 5 H and method 9. Method 6 and method 5 H are used for the main separation of the plasma, whereas method 9 is for the subfractionation of precipitate II + III.

Table IV-1 lists the various plasma fractions produced and indicates their respective components and ultimate uses.

Method 6 is used for the industrial production of plasma. The plasma for which this method was developed is obtained from bleedings in which one unit (500 me) of whole blood is collected in a vessel containing 50 me of 4 percent sodium citrate. After separating the cells from the plasma, the plasma is gently stirred, cooled and brought to a pH of 7.2.

The plasma then undergoes a series of centrifugation steps. The resultant supernatant and/or precipitate is chemically treated in preparation for the next centrifugation, is preserved and stored for future use, or is discarded.

Several manufacturers now use a simplified version of method 6. In this simpler system, the number of fractions is reduced and the total volume of the system is smaller. This modified procedure has been designated as method 5 H.

Table IV -1

Flowsheet of Protein Fractionation of Plasma

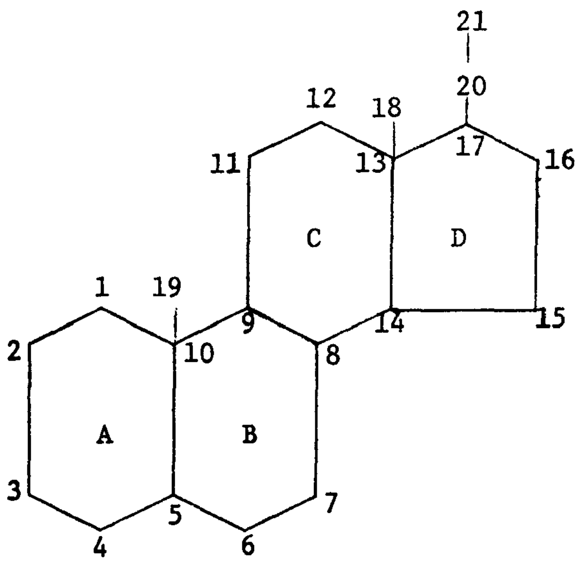
Fraction of Plasma		Components	Demonstrated Users
I		antihemophilic globulin	treatment of hemophilia
II + III	III-0	cholesterol: Phosphatides carotenoids; Vitamin A estrogens	
II + III-W	II	globulins and some B globulins	immune globulins against measles and infectious hepatitis; other antibodies
III	III-1	isoagglutinins	blood grouping
III-2-3	III-2	prothrombin (thrombin)	blood coagulation; hemo
III-3		(fibrinogen, which yields fibrin foam and film) plasminogen	in neurosurgery blood coagulation
IV-1		a-globulin; cholesterol: phosphatides; phosphatases	
IV-4		a- and b globulin; esterases hypertensinogen; some albumin	
VI		protein not precipitated	

FIGURE IV-4

STEROID HORMONES

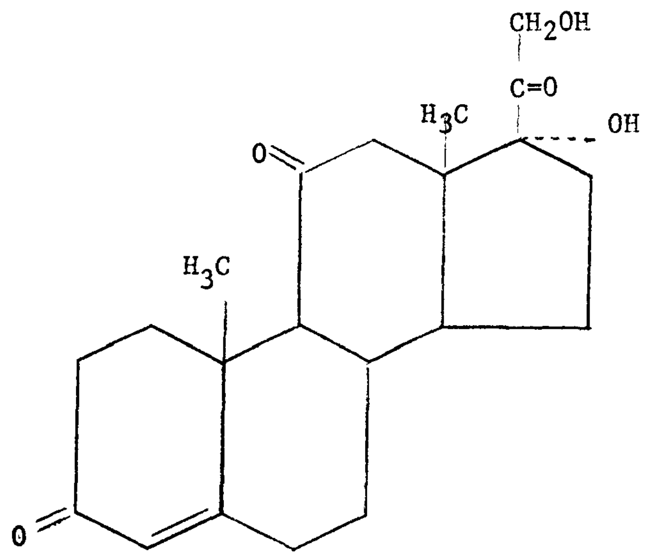
and

STEROIDAL SYNTHETICS



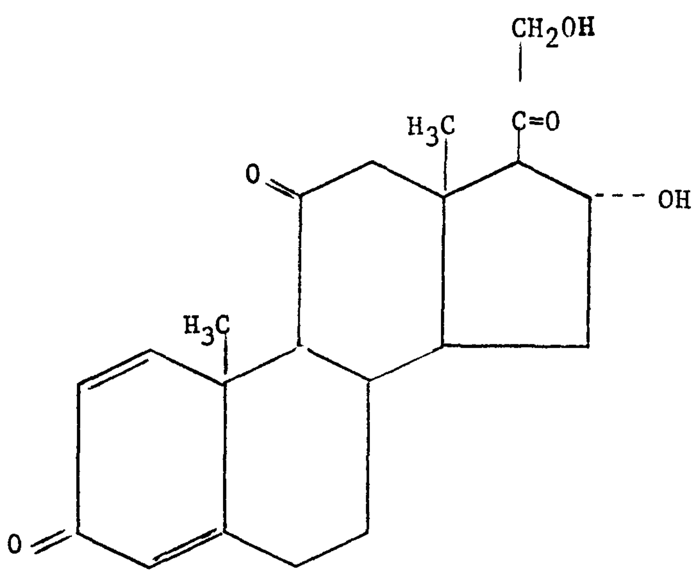
Cyclopentanophenanthrene

Nucleus



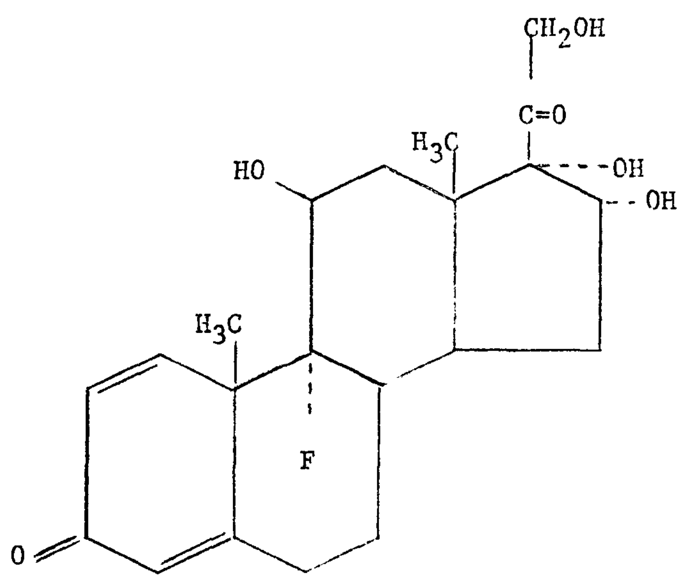
$C_{21}H_{28}O_5$

Cortisone



$C_{21}H_{26}O_5$

Prednisone



$C_{21}H_{27}FO_6$

Triamcinolone

The precipitate designated II + III, which is produced in the third step of method 6 and in method 5 H, is the starting material for method 9. This method is used to produce additional blood fractions and, as in methods 6 and 5 H, consists of a series of centrifugation steps to separate the desired plasma fractions.

In general, the production process for vaccines is lengthy and involves numerous batch operations. Figure IV-3 schematically outlines a typical vaccine production process. The primary unit operations include mincing, trypsinizing, centrifugation, incubation, freezing and drying. Liquid wastes associated with the process consist primarily of spent media broth, waste eggs, glassware and vessel washings and bad batches of production seed and/or final product.

Production of material extractions involves the processing of bulk botanical drugs and herbs. Typical unit operations used to manufacture products in this group include milling, grading, grinding, and solvent extraction. These manufacturing operations are usually carried out on a small scale and the quantity of wastewater generated is small. Most extraction processes practice solvent recovery and recycle and therefore the degree of contamination remaining in the washwater depends on the extent and efficiency of the recovery operations. The used plant tissues are generally incinerated with any waste solvents or are landfilled and therefore these wastes seldom enter the wastewater stream.

<u>Subcategory C - Chemical Synthesis Products</u>

The pharmaceutical manufacturing industry employs a greater variety of complicated steps in its manufacturing processes than almost any other chemical process industry. The complex chemical structure of many medicaments probably has a relationship to the even greater complexity of the ailments of the human and animal bodies which the products of the pharmaceutical industry are designed to ameliorate. For example, synthetic steroids have been synthesized, which though resembling the hormones in the body have no natural counterpart, but exert an effect comparable to those natural hormones. Such a material is prednisone which has the cyclopentanophenanthrene nucleus common to hormones. See Figure lV-4.

Each chemical synthesis process is itself a series of unit operations which causes chemical and/or physical changes in the feedstock or products. Flow sheets illustrating typical chemical synthesis of processes are shown in Figures IV-5 and IV-6. In the commercial synthesis of a single product

TYPICAL CHEMICAL SYNTHESIS PROCESS

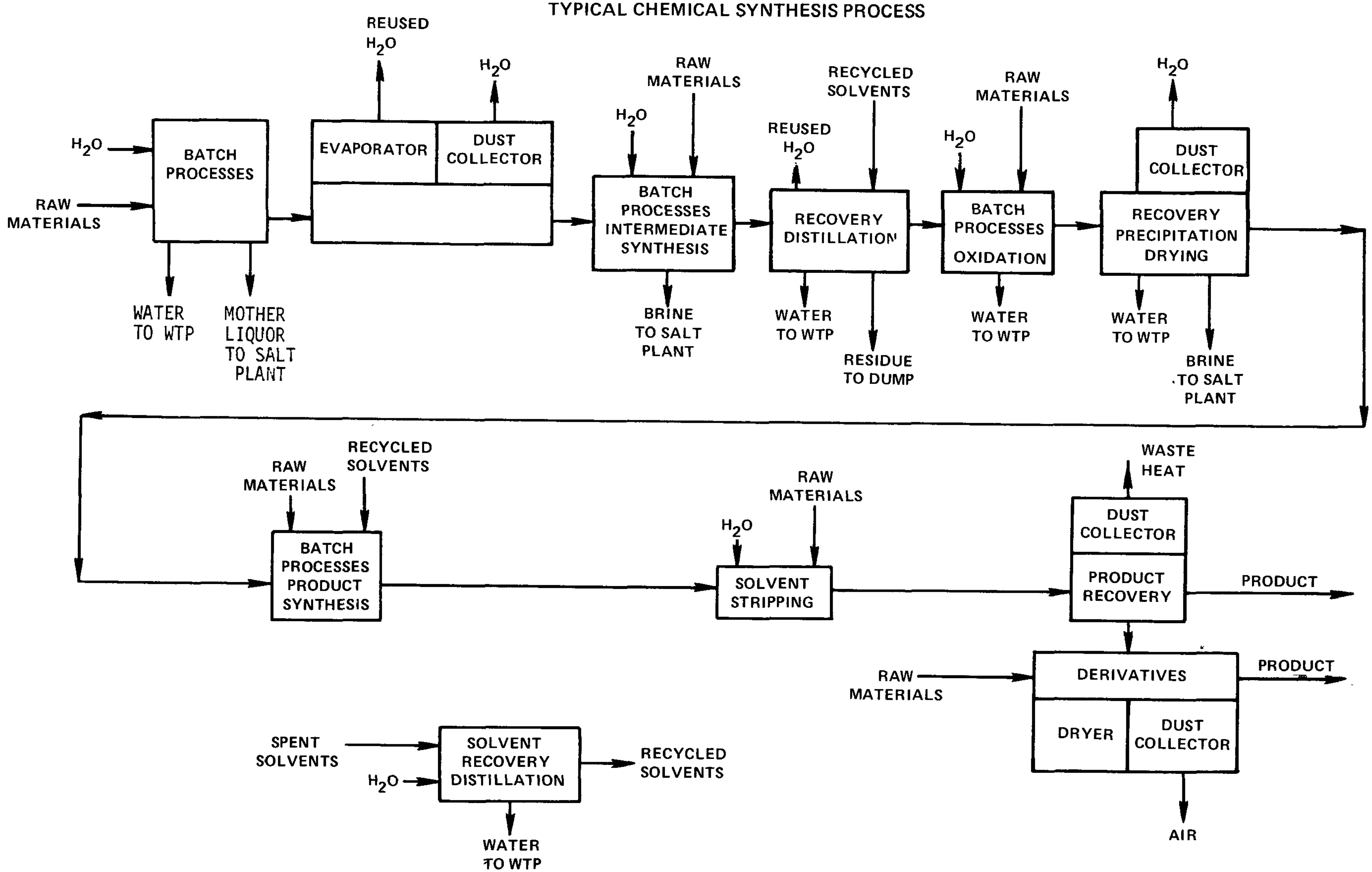


FIGURE IV 6

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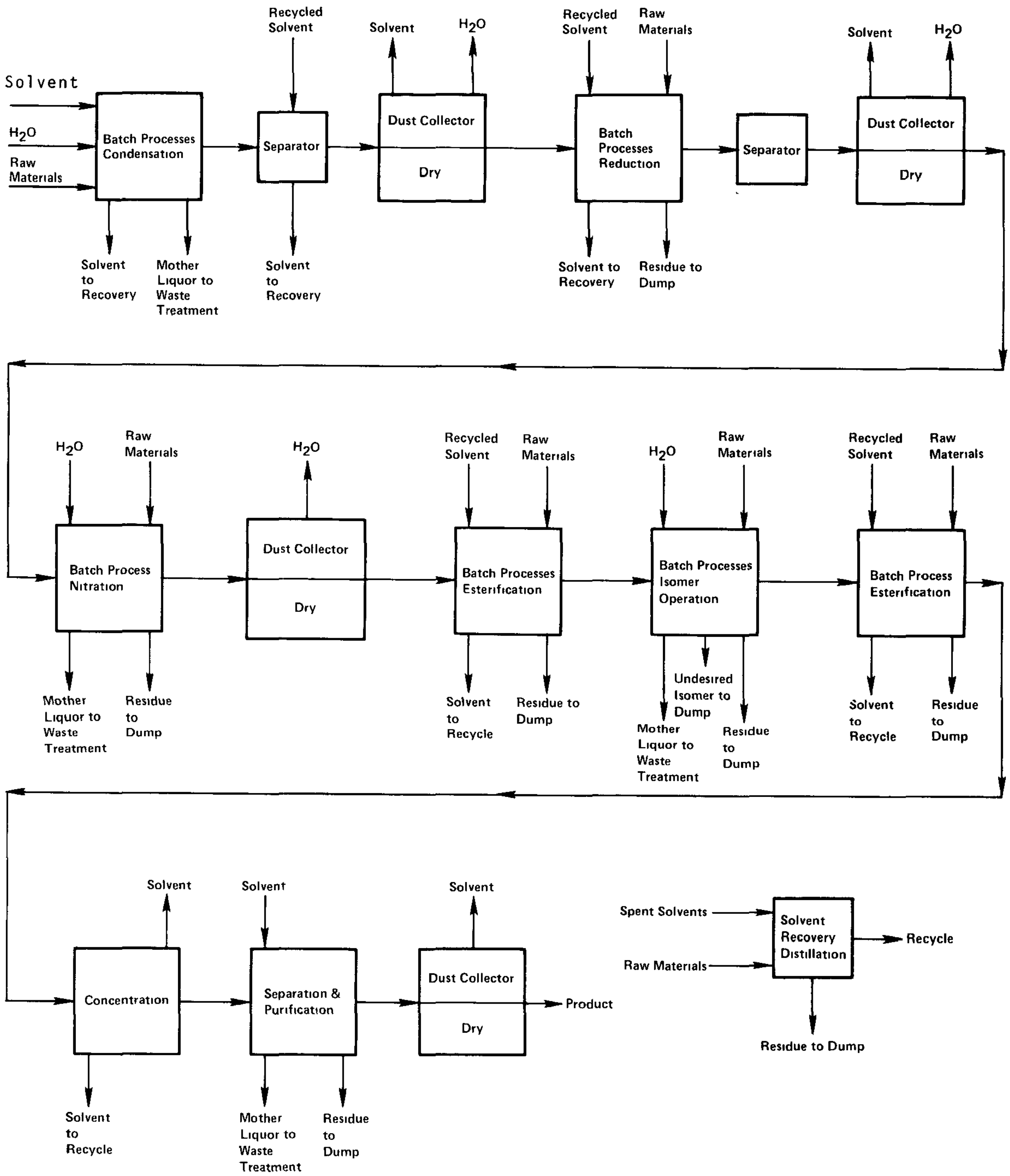
TYPICAL CHEMICAL SYNTHESIS PROCESS

(ANTIBIOTIC MANUFACTURE)



from a single feedstock, there generally are unit operations associated with the preparation of the feedstock, the chemical reaction, the separation of reaction products and the final purification of the desired product. Each unit operation may have drastically different water usages associated with it. The type and quantity of contact wastewater are therefore directly related to the nature of the various processes. This in turn implies that the types and quantities of wastewater generated by each plant's total production mix are variable.

In the manufacturing of fine chemicals, batch processes are frequently used for reasons of quality control, economic considerations, low product demands, FDA requirements, or specific manufacturing requirements. Batch operations are more easily controlled when varying reaction rates and rapid temperature changes are key considerations. This requires more supervision on the part of operators and engineers, since conditions and procedures usually change from the start to the finish. Batch operations with small production and variable products may also use the same equipment to make several different chemicals by the same type of chemical conversion. Hundreds of specific products may be manufactured within the same building. This type of processing requires the cleanout of reactors and other equipment after each batch. Purity specifications may also require extensive purging of the associated piping. Rapid changes in temperature during the batch sequence may also require the direct addition of ice or quench water instead of slower non-contact cooling through a jacket or coils.

Contact process waters from batch and continuous processes include not only water produced or required by the chemical reactions but also any water which comes in contact with chemicals within each of the process modules. Although the flows associated with these sources are generally smaller than those from non-contact sources, the organic pollution load carried by these streams may be greater by many orders of magnitude.

There are several possible major pollution sources in chemical synthesis production. If the reaction is carried out in a batch kettle or autoclave, then the washout solutions will be high in contaminant loadings. If distillation is done under vacuum, the process vacuum jet water will be saturated with the lighter components of the reaction mix. If filtration is involved, two possibilities exist. If the filter cake is unwanted, then there is a solid waste disposal problem. If the filtrate is the unwanted material, this portion is either collected for

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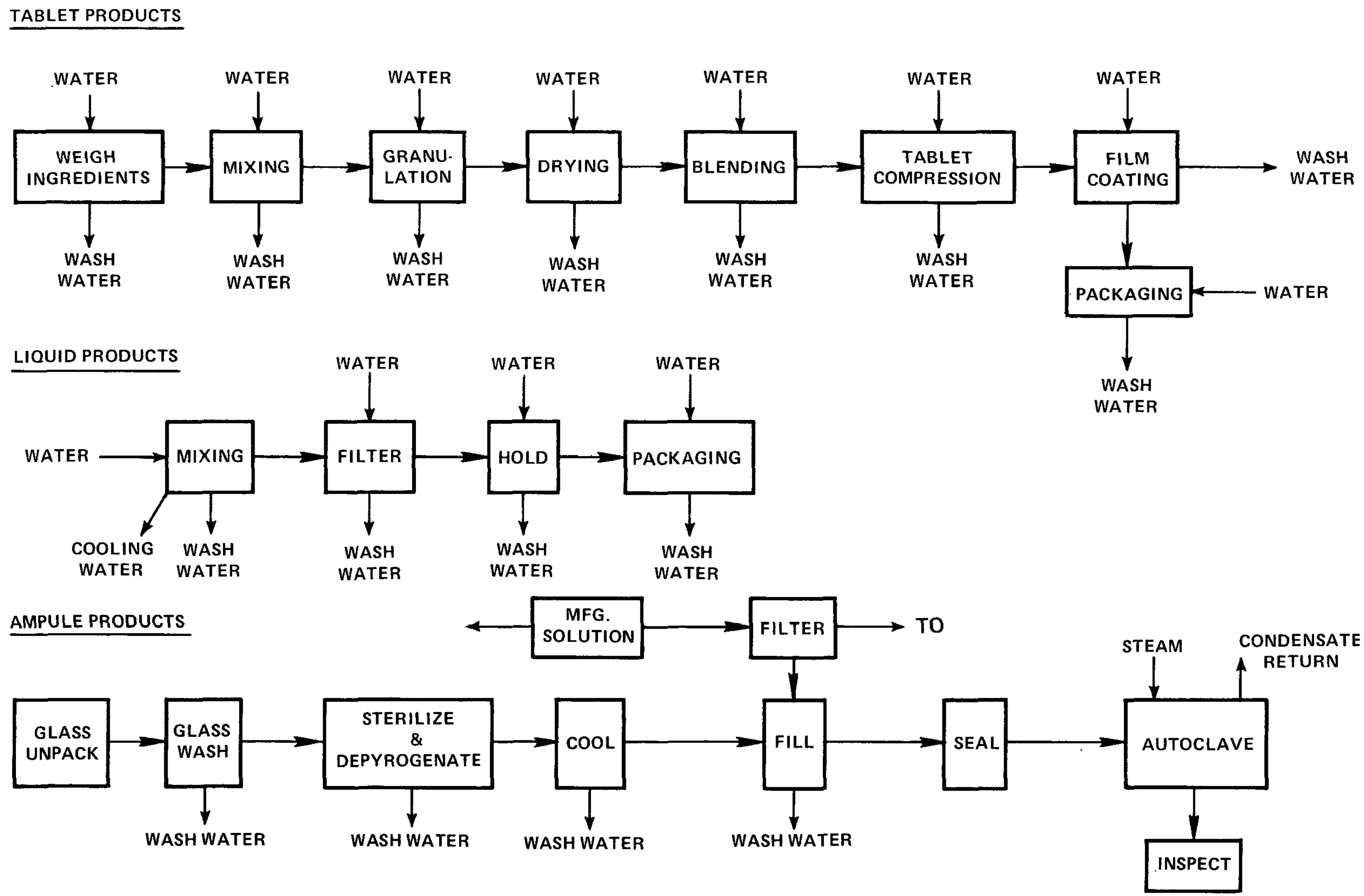
FIGURE IV -7

TYPICAL PHARMACEUTICAL FORMULATION PROCESSES



separate treatment or discharged to the process sewer, where it is combined with the main effluent for subsequent treatment. Since chemical reactions frequently involve acids or bases, an effluent needing pH adjustment may result, especially if one reactant is used in excess of stoichiometric proportions. Reactor effluent will sometimes contain emulsions from which the oil may be separable by pH adjustment.

Subcategory D - Mixing/Compounding and Formulation

Pharmaceutical formulation represents all the various operations that are involved in producing a packaged product suitable for administering as a finished, usable product form. It would include such things as mixing of ingredients, drying of granules, tableting, capsulating, coating of pills and tablets, preparation of sterile products and finally the packaging of the finished product. Figure IV-7 illustrates three typical pharmaceutical formulation processes.

In general, the specific unit operations of the formulation process cannot be considered serious water polluters, for the simple reason that they do not use water in any way that would cause pollution. It should also be pointed out that most pharmaceutical formulation plants work on an eight-hour day, five-day per week work schedule and the usage of water is limited primarily to that period. As a result of both the shorter work schedule and the lower water requirements per unit operation that characterize the plants in this subcategory, the amount of wastewater generated per pound of product is considerably lower for the plants in subcategory D than for the plants in the other categories. This can be seen from the survey results presented in Table V-1. In spite of this, however, there are a number of places where water pollution can be expected. Washup operations are always a potential pollution source. The application of too much water over too great an area can flush materials (into a sewer) that are unusual in terms of both quantity and concentration. Dust and fume scrubbers used in connection with building ventilation systems or, more directly, on dust and fume generating equipment, can be a source of water pollution, depending on the nature of the material being removed from the airstream. Most pharmaceutical manufacturing firms are compounders, special processors, formulators and product specialists. Their primary objective is to convert a desired prescription into tablets, pills, lozenges, powders, capsules, extracts, emulsions, solutions, syrups, parenterals, suspensions, tinctures, ointments, aerosols, suppositories, and other miscellaneous consumable forms. These operations can be classified as labor intensive and low in waste production.

Manufacturing descriptions for the different forms of pharmaceutical dosages are discussed in the subsequent paragraphs.

Tablets are formed by compaction of powders, crystals, or granulations. The various modifications which are possible can be seen in the following list:

Form of Tablet	Drug Release Characteristics
Plain compressed	Rapid or sustained
Coated	Rapid, delayed, sustained, and repeat action
Molded	Rapid

The process of plain compression tableting can be divided into the following three basic approaches: wet granulation, direct compression, and slugging.

For drugs which are not prone to degradation in the presence of moisture, the wet-granulation step has heretofore been the most widely used. The process consists of carefully blending the powdered ingredients (except for the lubricants and disintegrants) and then wetting the powder with a solution or dispersion of the binders. The damp mass is screened to form coarse granules and dried. The classic method of drying has been to spread the mass on trays and dry the granules in a hot-air oven. Recent advances in technology have produced a fluidized-bed drying technique in which the damp mass is placed into a cylindrical container with a screened bottom. Heated air is forced through the mass, causing the mass to be suspended in air and dried rapidly. This new method has reduced drying time to about one-fifth of that required by conventional methods. The fluidized-bed driers have also been modified so that the granulating fluid can be introduced into the air stream and can therefore granulate the powders and dry them in one operation. The dry granules are rescreened to about 20- to 40-mesh granules and then mixed with the lubricants and disintegrants. The granulation at this point is ready to be compressed into tablets.

The second technique for the preparation of tablets is direct compression. Much work has been carried out on this process in recent years because of the obvious advantage of reduced labor time. The process consists simply of blending the ingredients and compressing it into tablets.

The "slugging" technique is used only as a last resort in the case of drugs which cannot be wet-granulated because of instability and cannot be compressed directly. Slugging, as the title suggests, is the compaction of a powder blend into large tablets. They may be 1 or 2 inches in diameter and may weigh up to 30 grams. The large tablets are collected and ground up and converted into granules and then re-compressed into final tablet form.

The method for compressing granules into tablets, regardless of the method of manufacture, is basically identical. The granulation is fed into a die cavity. The fill is volumetric and consequently the weight must be controlled by changing the height of the lower punch, which regulates the volume available for filling. Since volume is directly measured, the necessity of having a free-flowing and uniform granulation becomes apparent. Once the cavity is filled, the upper punch compresses the powder mass into a tablet. After the tablet is ejected by the lower punch, the cycle is repeated.

Compressing equipment varies from small single-punch machines which have one upper and lower punch and a die, to large rotary tablet presses having up to fifty-five sets of punches and dies. The rate of production can vary from 100 tablets per minute on the single-punch machines to 4,500 tablets per minute on the larger presses.

In addition to conventional tablets, methodology has been developed to compress so-called layer tablets. In this method, two different granulations are fed into the machine. First, a portion of one granulation is compressed into a rather soft tablet and then a measured quantity of the second granulation is layered upon the partially-compressed tablet. The mass is then fully compressed, resulting in a layer tablet. This approach may be used for two reasons: 1) separation of incompatible ingredients and 2) preparation of sustained-action tablets where one layer provides the immediate-release dose and the second the slow, sustaining drug dose.

Tablets prepared as above can be coated to improve taste, stability, and appearance or to control the rate and site of drug release. The coating of tablets can be accomplished by three basic methods: pan coating, air-suspension coating and compression coating.

Pan coating is the classical technique in which cores, free from dust and broken tablets, are tumbled in pear-shaped pans. While the tablets are in motion, they are wet down with a concentrated syrup containing a film-forming agent such as gelatin, acacia, or methylcellulose. When all surfaces have been wet, a dusting or engrossing powder such as flour or powdered sugar is added and tumbled under a flow of warm air. This is usually repeated two or three times to coat the tablet rapidly and to round off the edges. After these coats, the tablets are usually dried overnight to prevent moisture from penetrating the core. This portion of the process is generally called subcoating. The process is continued by repeated applications of the heavy syrup without dusting powder to smooth out the tablet surface. Color coats are applied if desired and then the tablet is polished with carnauba wax in a canvas- or wax-lined pan. Pan coating is the standard method of tablet coating and as a rule the finished coated tablet weight is double that of the uncoated core.

As in the case of the compression of tablets, recent advances in the technology have greatly modified coating procedures. The process of film coating has achieved great popularity. In this method, tablets are given a thin coat of a polymeric material, either by repeated application by hand or automated by means of a programmed system. Air-suspension coating, known as the Wurster process, is suited for film coating. The cores are placed in a cylindrical chamber and "fluidized" (suspended in a stream of air). The coating solution is atomized into the air stream. Because of rapid evaporation of the solvent, the coating material is continuously deposited upon the tablet. The time required for coating in this method is about one-tenth that for conventional methods.

The coatings discussed so far have all had one common factor, i.e., the coating materials were either suspended or dissolved in a solvent. Another method of coating is compression (or dry) coating. In this process, a core tablet is prepared and then an outer coating is compressed around the inner tablet. This results in what might be called a tablet within a tablet.

Molded tablets are prepared by molding a damp mass into the general shape of tablets.

Most individuals refer to tablets of any type as "pills". Actually, pills are a definite and distinct class of dosage form and were the forerunner of today's tablet. Pills combine a drug and an "excipient" which, when damp, gives the mass a doughlike consistency. The mass is divided into dose units and then rolled into balls and allowed to dry.

Although pills can be produced mechanically, the inherent problems of accuracy as compared to tablet production have caused a dramatic decrease in their use. The basic process is to mix the drug with the excipient and then dampen this with some agent such as acacia syrup, glycerol, sugar syrup, or synthetic gums. The plastic mass is rolled into long pipes of uniform diameter and then cut into pieces equivalent to one dose of the drug. The divided portions pass between two belts and are rolled into spherical pills, dusted with a powder to prevent sticking together and finally dried. The finished pills may be coated in the same manner as tablets.

Next to tablets, capsules rank second as the most widely used solid oral dosage form. They have an advantage over tablets in that they do not require the addition of binders and disintegrants. Capsules fall into two basic categories, hard and soft. Hard gelatin capsules are prepared in two sections, one of which slips over the other. They are prepared empty and filled with powder when needed. The soft gelatin capsule is made with gelatin and glycerol and retains its plasticity even when dry. The soft capsules are not prepared in advance but as part of the manufacturing process.

The manufacture of hard gelatin capsules is a rather precise technique, since the seal of the capsule depends upon the tight fit of the top over the body of the capsule. The process consists of dipping steel pins into a solution of gelatin maintained at a precise temperature. When the pins are removed from the bath, a film of gelatin adheres to the pins. The temperature is critical, since the viscosity of the gelatin is affected by temperature and this determines the thickness of the film adhering to the pins and consequently the wall thickness of the finished capsule.

When the capsule has been dried, trimmed to proper length and removed from the pin, the upper and lower portions are joined. The sizes of the capsules vary greatly from those holding approximately 30 mg to those holding several grams for veterinary use. The colors of the capsules can be controlled by added dyes or pigments.

Capsules are filled by various pieces of equipment. Machines separate the upper and lower portions of the capsules, filling the powder into the lower half and then rejoining the capsule components. Since the fill is volumetric, the ratio of drug to diluent must be adjusted to obtain the correct dose of drug for a specific capsule size. After the capsules are filled they are usually cleaned with air and tumbled with sodium chloride to remove any dust which may cling to the capsule. They may subsequently be imprinted with a name or trademark for identification.

Although the majority of soft gelatin capsules contain non-aqueous solutions or soft masses containing the drug, powders can be filled into this type of dosage form. In soft gelatin capsule manufacture, two continuous films of gelatin are passed between two rotary die plates which contain cavities, each corresponding to one-half of the capsule. As they come together, the mass or liquid is injected into the partially-sealed capsule. Upon further rotation, the edges are pressure-sealed and the capsule is cut out of the ribbon. If the capsules are to be filled with powders, one ribbon is passed under a hopper containing the powder, which is fed into a cavity created when the gelatin is molded into the die by vacuum. After filling, the second ribbon seals the capsules in a manner analogous to that for the liquid capsules.

Although aerosols have been used for over twenty years for dispensing insecticides and insect repellents, the usefulness of this medium for the dispensing of drugs has been recognized widely only since the 1950's.

Aerosols are usually manufactured by the cold-filling method. The propellants are usually fluorinated hydrocarbons of varying compositions having different vapor-pressure and boiling-point characteristics. Generally, the solution or suspension of the propellants and the drug is chilled to reduce the vapor pressure and the solution is filled volumetrically into suitable containers. The valves are then firmly attached and sealed to the container. Care must be exercised in this operation to exclude moisture, since the propellants are hydrolyzed by moisture to yield corrosive products. Generally, the operations are carried out in dehumidified areas. The finished containers are usually placed in water and defective units are detected by the appearance of bubbles.

An alternative method of manufacture is to seal the valve to the empty container and then force the solution through the valve under pressure. This method is useful for the preparation of small quantities.

Liquids may be simple solutions, syrups, elixirs, or suspensions. These preparations are usually manufactured in jacketed glass-lined or stainless-steel vessels similar to chemical reactors. The solutions are filtered under pressure through plate filters and then pumped into suitable storage tanks prior to filling. At this stage the bulk product is usually sampled for analysis and control of physical specifications.

The manufacturing processes for suspensions and emulsions are similar to that for solutions, except that after dispersion by simple mixing the system is passed through a homogenizer or colloid mill. These units may force the dispersion through a small orifice under high pressure or pass the dispersion between two plates, one stationary and the other rotating at high speed. The aperture between the plates is adjustable to vary the shearing action of the mill. Advances in ultrasonics have made it possible to utilize this form of energy in production for dispersion of substances. This method has proved useful for both suspensions and emulsions.

The manufacturing of ointments involves melting a base material and then blending in the drug. The mass is allowed to cool and is then passed through roller mills, high-speed colloid mills, or mills of the rotor and stator type. In the last case, adequate cooling of the mill is important, since too much heat buildup will cause the ointment to melt, resulting in a non-homogeneous product.

Creams are manufactured in a similar manner, except that the products consist of two phases and therefore each phase must be heated separately and the drug incorporated into one of them. The two phases are mixed with rapid stirring and are stirred continuously until cool.

The manufacturing process for suppositories consist of melting a loose material, dispersing the drug and pouring the mixture into pre-chilled molds. This can be carried out by manual or automatic methods. Suppositories can also be made by compression of a powdered base in which the drug has been dispersed. The latter method is not used in full production unless specifically required by the nature of the drug.

Subcategory E - Microbiological, Biological and Chemcial Research

A new drug normally takes five to six years to reach the market, resulting in an average cost of five million dollars. On the average, 5,000 chemical compounds are investigated before one is found that is therapeutically useful. Research in the pharmaceutical industry is a team effort. The industry employs pure and applied scientists of almost all disciplines from mathematicians and physicists to pharmacologists, pharmacists, chemists and medical practitioners. Because of the high cost of a new drug and the general importance to the public health, companies are mainly interested in cures for the more common ailments. Nevertheless, many remedies for rare diseases and diagnostic agents have come from the laboratories of the pharmaceutical industry. The three areas of research are chemical, microbiological and biological. The wastes generated from these various research areas range from exotic chemicals to animal wastes.

Scientists of various disciplines, including pharmacology, biochemistry, organic and physical chemistry, zoology and bacteriology, may be involved in the preclinical testing and evaluation of a new drug. Meaningful biological tests using laboratory animals such as rats, dogs and monkeys are designed to test the pharmacological actions of the chemical entities. Potential antibacterials, antivirals and related drugs must be tested against a broad spectrum of microorganisms. If these preliminary tests are promising, short- and long-range toxicity studies must be performed and dose levels suitable from both the pharmacological response and toxicity points of view must be determined.

Laboratory animals are used extensively by pharmaceutical research facilities. The types of animals used include dogs, cats, monkeys, rabbits, guinea pigs, rats and mice. The animal colonies where these test animals are housed can be a major wastewater source. The animal cages are usually dry cleaned and the residue washed into the plant sewer system. The collected feces and any animal carcasses are incinerated or landfilled if the waste matter is not infected. The exhaust gases from the incinerators pass through wet scrubbers and the scrubber blowdown is subsequently discharged to the plant sewer system.

<u>General Utilities and Services</u>

At first glance, a pharmaceutical manufacturing plant often appears to be a chaotic maze of equipment, piping and buildings that is totally unlike any other facility, even those which manufacture the same product. Nevertheless, there are certain basic components common to almost all chemical plants: a process area; storage and handling facilities for raw materials, intermediates and finished products; electrical, steam, air and water systems with associated sewers and effluent treatment facilities; and, in most cases, a laboratory, an office, control rooms and service roads.

The storage facilities associated with any pharmaceutical manufacturing plant obviously depend upon the physical state (i.e. solid, liquid, or gas) of the feedstocks and products. Storage equipment frequently utilized includes: cone-roof tanks, with or without "floating" roofs, for storage of liquid hydrocarbons; cylindrical or spherical gas-holding tanks; underground and above ground storage tanks; and concrete pads or silos for storage of solids.

Wastewater emanating from storage facilities normally results from storm run-off, tank washing, accidental spills and aqueous bottoms periodically drawn from storage tanks. Although the generation rate is sporadic and the volume small, these wastewaters have in most cases contacted the chemicals which are present in this area. For this reason, they are normally sent to a process sewer and given the same effluent treatment as contact-process wastewaters.

Utility functions, such as steam supply, deionized water, ice water supply, hot water supply and cooling water, are generally set up to service several processes. Boiler feed water is prepared and steam is generated in a single boiler house. Non-contact steam used for surface heating is circulated through a closed loop, making varying quantities available for the specific requirements of the different processes. The condensate is almost always recycled to the boiler house, where a certain portion is discharged as blowdown.

The three major uses of steam generated within a pharmaceutical manufacturing plant are:

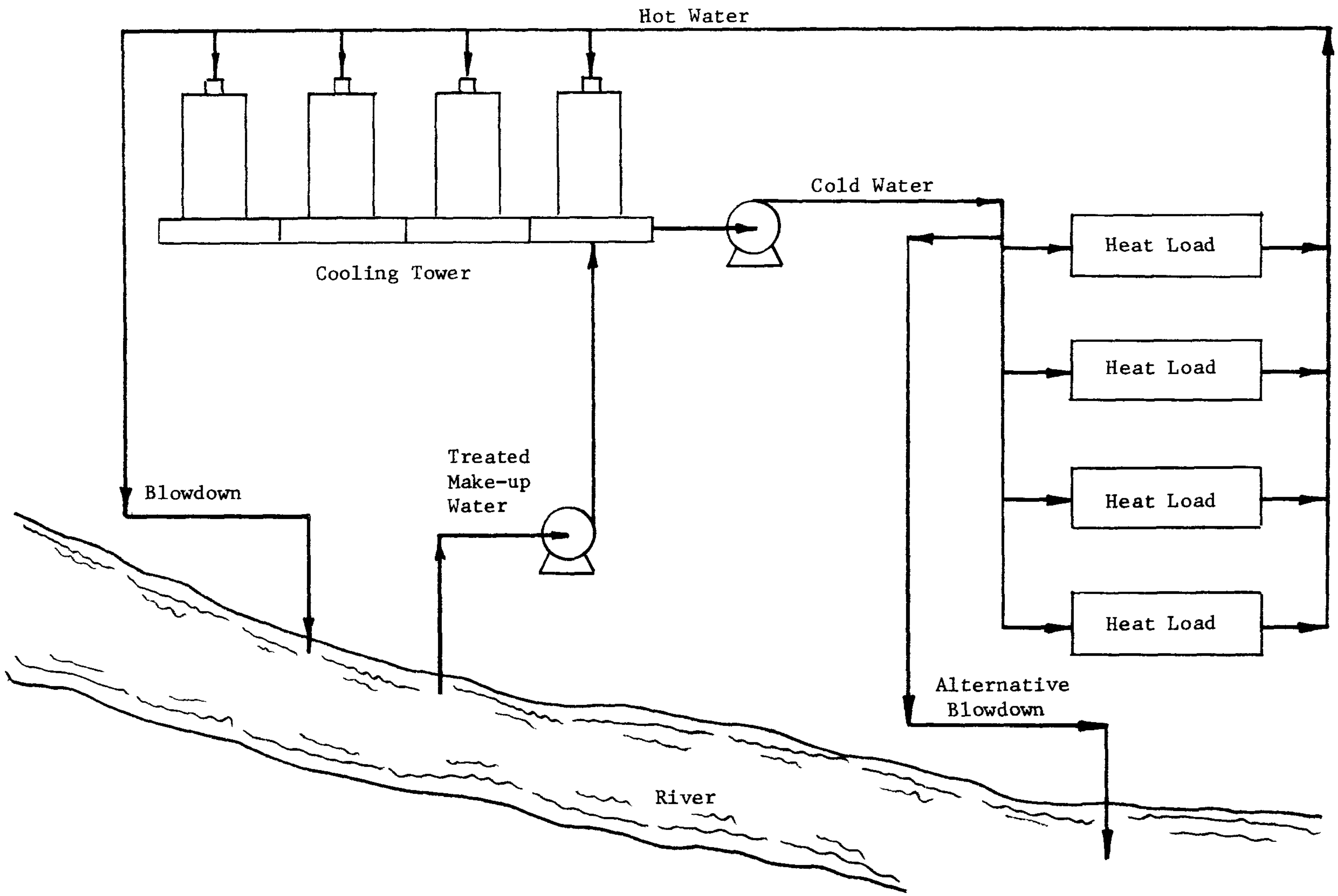
1. For non-contact process heating. In this application, the steam is normally generated at pressures of 125 to 650 psig, or low-pressure steam at pressures of 5 to 50 psig, for heat-sensitive products.

2. For power generation, such as in steam-driven turbines, compressors, and pumps associated with the process. In this application, the steam is normally generated at pressures of 650 to 1500 psig and requires superheating.

3. For use as a diluent, a stripping medium, or a source of vacuum through the use of steam-jet ejectors. This steam actually contacts the

Figure IV - 8

EVAPORATIVE COOLING WATER SYSTEM



hydrocarbons in the manufacturing processes and is a source of contact process wastewater when condensed. It is used at a substantially lower pressure than the foregoing and frequently is exhaust steam from one of the other uses.

Water conditioning or pretreatment systems are normally part of the utilities department of most plants. From the previous discussions, it should be obvious that the required treatment may be quite extensive. Ion-exchange demineralization systems are very widely employed, not only for conditioning water for high-pressure boilers, but also for conditioning various process waters. Clarification preceding an ion exchange operation may be employed. In some cases, a demineralization system is dedicated to a single processing step with a high demand for continued water and, therefore, is operated as part of that production unit.

Non-contact cooling water also is normally supplied to several processes from the utilities area. The system is either a loop which utilizes one or more evaporative cooling towers, or a once-through system with direct discharge.

A closed system is normally used when converting from once-through river cooling of plant processes. In the closed system, a cooling tower is used for cooling all of the hot water from the processes. Figure IV-8 illustrates this method. With the closed system, makeup water from the river is required to replace evaporation loss (at the tower), drift and blowdown. Drift is droplet carry-over in the air (as opposed to evaporative loss). The cooling tower industry has a standarized guarantee that drift loss will not exceed 0.2 percent of the water circulated. Blowdown to a sewer or river is necessary to avoid a build up of dissolved solids. Although blowdown is usually taken off the hot water line, it may be removed from the cold water side to comply with regulations that limit the temperature of cooling water discharged. Blowdown from a tower system will vary, depending on the dissolved solids concentration in the make-up water and the cycles of concentration maintained in the system. Generally, blowdown will be about 0.3 percent per 10°F of cooling, in order to maintain a dissolved solids concentration in the recirculated water of three to four times that of the make-up water.

The quantity and quality of the blowdown from boilers and cooling towers depend on the design of the particular plant utility system. The heat content of these streams is purely a function of the heat recovery equipment associated with the utility system. The amounts of waste brine and sludge produced by ion exchange and water treatment systems depend on both the plant water use function and the intake water source. None of these utility waste streams can be related directly to specific process units.

Quantitative limitations on parameters such as dissolved solids, hardness, alkalinity and temperature, therefore, cannot be allocated on a production basis. The limitations on parameters like these, which are associated with non-contact utility effluents, are being established in the effluent guidelines for the steam supply and non-contact cooling water industry.

The service area of the plant contains the buildings, shops and laboratories in which most of the plant personnel work. The sanitary wastes from this area obviously depend on the number of persons employed. It should be noted that most bulk chemical synthesis plants run continuously and have 3 operating shifts per day. There are also wastes associated with the operation of the laboratory, machine shops, laundry, etc. Depending on the size of the plant, there may be tank car and/or tank truck cleaning facilities which could add to the process wastewater load. The wastes from the service area normally are combined with the wastes from the process area prior to treatment.

Basis for Assignment to Subcategories

The subcategorization of the pharmaceutical manufacturing point source category assigns pharmaceutical production facilities to specific subcategories according to the manufacturing processes which they utilize. The subcategories selected were:

Subcategory	Description	SIC
A	Fermentation Products	2833
B	Biological and Natural Extraction Products	2833
C	Chemical Synthesis Products	2833
D	Mixing/Compounding and Formulation	2834
E	Research	--

This subcategorization of the pharmaceutical manufacturing point source category was based on the nature of manufacturing processes, raw materials, and products and the wastewater quantities and qualities generated by each of these production subcategories. Table V-1 indicates the plant production levels, wastewater flow rates and RWL's which typify each of the subcategories. The characteristics of the wastewaters generated by point sources falling into each of the subcategories is also discussed in Section V. Subcategory C (chemical synthesis) was further divided according to manufacturing processes. Although wide variance in raw waste loads originally suggested a classification of antibiotics by synthesis (C2) the single example of thermal oxidation treatment of C2 wastes did not justify separate consideration of C1 and C2 wastes.

For subcategory E, which encompasses research facilities, a different measure was used for establishing effluent limitations, i.e., total enclosed building floor area. The raw waste loads computed on a total enclosed building floor area basis were comparable. The number of test animals supported by a research facility was also investigated as a basis for calculating RWL levels for category E; however, this parameter did not prove to be as consistent as total enclosed building floor area.

A possible future classification of Subcategory E into E1 (Research - Microbiological, Biological, Chemical) and E2 (Research Farm) is being studied, with the possibility of expressing limitations in terms of large-animal weight or population equivalents.

Pharmaceutical Plant Summaries From Field Survey

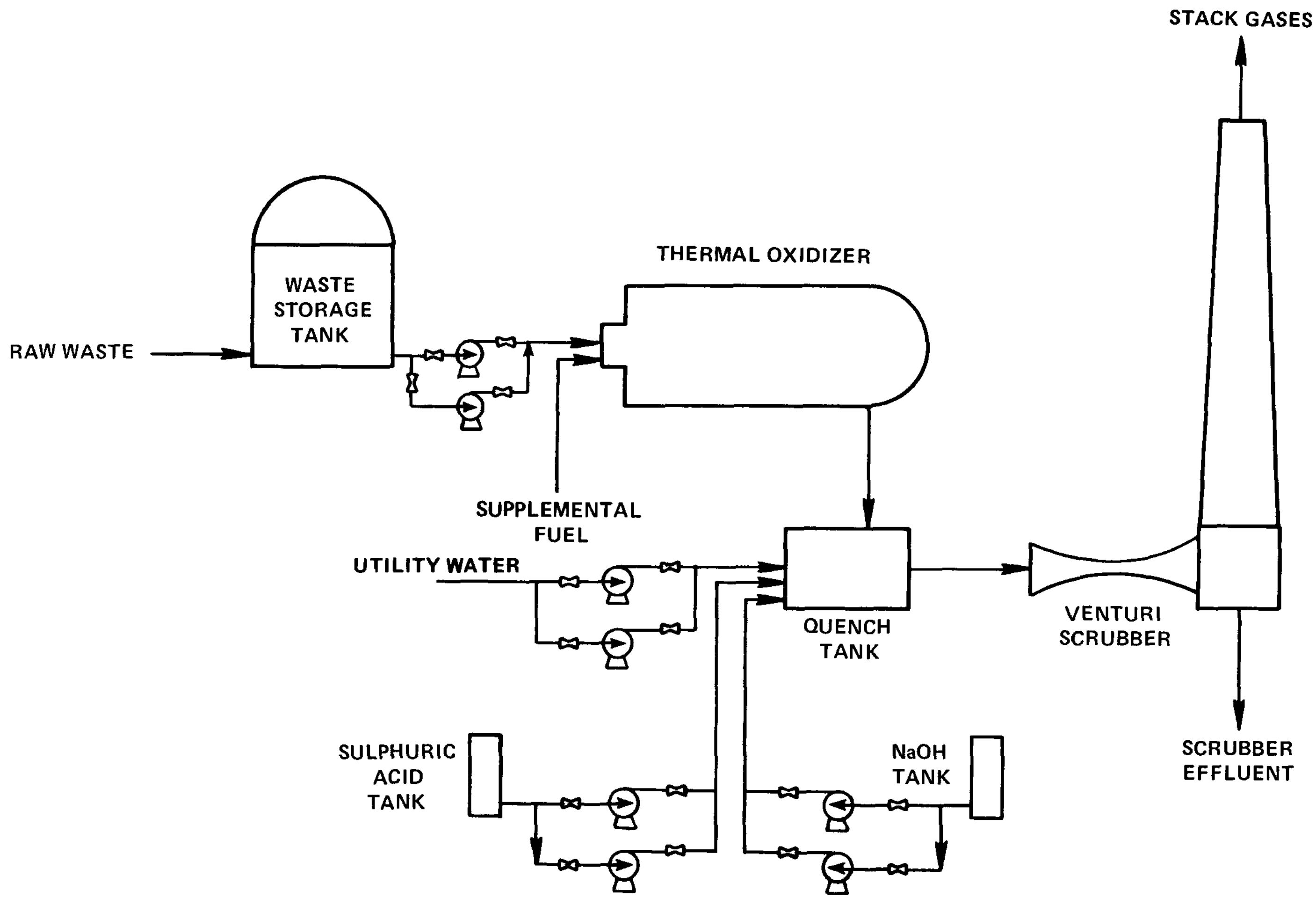
Plant identification numbers were assigned from number 1 through number 26. Plants numbered 1 through 20 in the initial survey by Roy F. Weston, Inc., (RFW) retained those original identification numbers in the follow-on work by Jacobs Engineering whether or not a plant was revisited. Plants assigned numbers 21 through 26 were checked only by Jacobs Engineering for the purpose of this overall study. Note that plant numbers 6, 7 and 13 were abandoned because scheduled plant visits did not occur as originally planned. Plant descriptions and data summaries are as follows:

Plant 1

The operations of this plant are in the A and C subcategories.

FIGURE IV- 9

Typical Thermal Oxidizer Configuration



A unique method of wastewater disposal is used at this plant; it is evaporated and incinerated. This is accomplished in part in two John Zink Thermal Oxidizers. This type of unit is an incinerator in the form of a large horizontal cylinder. A "primary feed", in this case essentially the nonaqueous liquid waste stream from the manufacturing processes, is sprayed axially into one end. A short distance downstream four jets around the circumference introduce secondary feed, consisting of watery wastes. This operation not only destroys the organic matter in those wastes, but also serves to moderate the temperature, which otherwise would be higher than the equipment could tolerate. However, supplementary fuel is necessary if the entire volume of liquid wastes is to be incinerated. See Figure IV-9 for typical schematic for a thermal oxidizer and ancillary equipment.

The plant also has a triple-effect evaporator and a Carver-Greenfield waste heat boiler, burning certain oily wastes as well as watery wastes. A rotary kiln incinerator destroys solid wastes.

Small amounts of pollutants are present in condensates and in water used for scrubbing the stack gases and in some of the cooling waters. The overall efficiency of BOD reduction is rated at about 99%.

The treatment process is seen in a favorable light from the standpoint of pollution control, but in view of the fuel requirement and other operating costs, it is not yet assured that it is a practical operation for the industry generally. The company has other plants manufacturing the same products, but in no other place is the same method used for wastewater treatment.

Samples of various streams were taken by RFW on October 15 and 16, 1974 and were analyzed both by RFW and the company. A series of samples were taken for analysis by the PJB Laboratory of Jacobs Engineering Company on April 20, 1976.

It is difficult in this plant to secure results for concentrations in raw waste streams that will permit comparison with other plants, since the processes of handling the wastes are so different. RFW secured figures of 12,500 mg/l for BOD and 31,100 mg/l for BOD in the wastewater stream from the fermentation operations. The high concentration in comparison with most plants is due, no doubt, to frugal use of water to minimize the fuel requirement for evaporation. No figures were derived for the wastes from chemical synthesis and no usable information of this type was obtained from the PJB tests.

Plant 2

This is a large plant with fermentation and chemical synthesis operations. The wastewater treatment plant has grown by successive expansions, and in consequence it now includes a complex array of basins, pipes, aerators, chemical feed equipment, etc. This is not a disadvantage, since it allows considerable flexibility of operation.

A John Zink Thermal Oxidizer is used fcr the disposal of the non-aqueous waste stream. The strongest of the aqueous streams serves as secondary feed to the oxidizer; in this way as much as 15% of the COD in the wastewater is incinerated.

There are essentially three wastewater treatment plants. For the purposes of this discussicn they are designated as the "100", "200" and "300" plants.

<u>100 Plant</u> - an activated sludge plant to treat a wastewater stream from fermentations and associated extraction operations. When sampling was undertaken on May 15, 1974, the 24-hour flow was 314 cu m The plant includes a primary clarifier, two aeration tanks in parallel and two secondary clarifiers. The effluent of these facilities then goes to the 200 plant.

<u>200 Plant</u> - the principal waste stream entering this plant, amounting to 1280 cu m/day, is described as "sanitary wastes." The stream includes human wastes, but the load comes principally from the rinsing cf equipment and from other wastewater sources in the production areas. With the addition of the discharge from the 100 plant, the influent flow is 1594 cu m/day exclusive of the return of centrate from sludge processing. Data from the company indicates that this returned flow is normally about 67 gpm, or 360 cu m/day. The treatment plant is basically of the activated sludge type.

<u>300 Plant</u> - this treatment plant received a flow (on April 16, 1976) of 500 cu m of wastewater from the chemical synthesis operations. This included 210 cu m of wastes trucked in from another pharmaceutical plant on that day. The 18-month average flow through the 300 plant in 1973 and 1974 was reported to be 960 cu m/day. The treatment plant includes a relatively small equalization tank, chemical feed

equipment for pH adjustment, clarifier, three aeration tanks with volumes which total 1340 cu m, clarifier and two aerated basins (referred to as lagcons and covered with inflated membranes to diminish heat losses). These lagoons provide an additional aèration time of about three days.

The stream from this plant joins the combined flow from the rest of the system and the total flcw passes through a final clarifier and then discharges frcm outfall 001. Surface runoff and certain cooling waters discharge by way of other outfalls.

There is a pesticide manufacturing operation with a small wastewater flow that is treated by carbon sorption and then added to the other flows. The residual impurities make a negligible contribution to the raw waste load of the total plant.

Records of the company for the period from January 1973 to June 1974 show the following averaged results:

18-month averages, January 1973 - June 1974

Effluents of the Treatment Plants

	Spent broth System Stream 100	"Sanitary" Wastes Stream 200	Chemical Wastes Stream 300	Total
Flow, cu m/day	810	1430	948	3,188
COD, kg/day	11,900	4600	19,600	36,100
mg/l	14,700	3200	20,600	
BOD, kg/day	7,140	2360	9,450	18,950
mg/l	8,820	1650	9,950	

Struzeski calculated removal efficiencies for the overall system in March and May, 1974 with average results of 76% for BOD and 66% for COD.

Because of return flows from the centrifuge and other complications due to the flow patterns, raw waste loads are not easily calculable. The Roy F. Weston Co. made a six-week study of the plant (May and June 1974) and estimated, by comparison with company data, that the corrected raw waste loads were as follows:

Stream	BOD, kg/day
Fermentation	7,900
Miscellaneous ("Sanitary")	1,800
Chemical Synthesis	10,700
Total:	20,400

Samples were taken by PJB personnel on April 14, 1974 and analyzed, with results as shown on the laboratory report sheets. Flows were probably atypical on that day, as judged by the information submitted. The results do not yield any refinement of the deductions based upon the earlier studies.

The company reports that equipment and operation modifications have led to progressive improvement of efficiency. Data submitted for the year 1975 showed 9,770 kg/day of raw BOD load from the antibiotic system (treatment plants 100 and 200) with a BOD removal efficiency of 92.8%. The chemical system had a raw BOD load of 5,380 kg/day and an efficiency of 91.0%. These figures are based upon daily tests (nominally 365 results).

The company submitted monthly averages of suspended solids in the effluent streams from the antibiotic area (the 100 + 200 system) and from the chemical synthesis area, with 1975 annual averages as follows.

	Antibiotic Area	Chemical Synthesis Area
Flow, cu m/day	810	2,400
Effluent TSS, mg/l	666	362
Effluent TSS, kg/day	1,600	2,930

Plant 3

The activities in this plant are in subcategories B and D. The manufacturing activity consists of production of bacterial and virus vaccines, processing of botanical products as well as gland derivatives and manufacturing and processing of a broad line of pharmaceutical preparations.

Subcategory B activities, manufacturing pharmaceuticals and biologicals, primarily take place in one building, while mainly subcategory D activities, packaging and filling, take place in another separate building. In addition, the complex includes research, a pilot plant, warehouse and offices.

All sanitary, boiler and process wastewaters are collected by a combined sewer system that connects to the municipal sewer system. Cooling water is taken from and returned to a river. The major source of liquid process waste is from floor washings and the washings of equipment and vessels between batch operations.

Because of the inaccessibility of the sewer line from one building, waste samples could only be taken from the building in which mainly subcategory B activities take place. Two eight-hour composite samples were taken on September 24, 1974. The sampling coincided with two eight-hour shifts. The observations were as follows:

Flow, cu m/day	1,530
BOD, mg/l	178
COD, mg/l	416
SS, mg/l	4
TOC, mg/l	122

RFW estimated net industrial raw waste loads by making deductions for human waste loads, with results as follows:

	Total Flow	Net Industrial
Flow, cu m/day	1,530	1,492
BOD, kg/day	273	265
COD, kg/day	636	617
SS, kg/day	74.8	67.1
TOC, kg/day	202	194

Plant 4

Subcategories A and C define the type of operations in this plant.

The treatment plant provides equalization and neutralization basins with a retention time of 9 hours. The flow then goes to a plastic-media bio-filter, 15 m in diameter by 6.6 m high (1,180 cu m), followed by activated sludge treatment. The aeration period is 17 hours. Waste sludge is filtered and incinerated, along with mycelia from the fermentation plant. Wastewater flow averaged 3,800 cu m/day in 1973-1974.

Historical data presented by Struzeski (14 mo.) shows an average raw BOD concentration of 1,870 mg/l in an average flow of 3,840 cu m/day. The average raw BOD load is 7,080 kg/day. The data also show an average BOD reduction of 79.7%. This includes contaminated cooling waters that bypass the biofilter-activated sludge plant; thus, the efficiency of the plant is doubtless higher than 80%.

Weston's data give the following information (results in mg/l):

1974	COD Inf.	COD Eff.	BOD Inf.	BOD Eff.	SS Inf.	SS Eff.
22 Sept.	3260	576	1560	60	332	109
23 Sept.	3230	823	1300	350	556	308
24 Sept.	4510	470	2200	14	1270	64
21 Nov.	3050	593	600	282	936	143
22 Nov.	1840	700	876	68	598	87
	3180	632	1307	155	728	142
	80% removal		88% removal			

Raw waste loads based on Weston's data are presented below:

	Kg/day BOD	Kg/day COD	Kg/day TSS	Kg/day TDC
Fermentation flow = 1040 cu m/day	4520	7300	635	2190
Chemical synthesis flow = 4150 cu m/day	2330	9340	3210	4070

Plant 5

The activities of this plant are in subcategories D and E. The products manufactured are primarily ethical and proprietary pharmaceuticals formulated or prepared for human consumption. The manufacturing operations include formulation and compounding of liquid and dry products, coating of dry products, preparation of ampules and packaging of final products. All manufacturing is done by batch operations. In addition to manufacturing, the plant has administrative and research facilities.

Approximately 1000 persons are employed at the plant complex. Manufacturing employees work in two shifts, while administrative and research employees work single shifts.

The major sources of liquid process wastes in all process operations are floor washings and equipment and vessel washings between batch operations. Cooling water bleed-off and boiler blow-down are also discharged into the process wastewater sewer. Storm water runoff is diverted to a nearby stream.

Research activities, involving development and testing of new products, take place in two buildings which house large colonies of animals. The bulk of the liquid waste from these facilities consists of cage washings and general laboratory wastes.

Both sanitary and process waste flows are treated by an activated sludge treatment process. The treatment plant includes a 76 cu m primary settling tank, two 170 cu m equalization tanks, two 200 cu m aeration tanks in series, each with an air flow of 13 cu m/minute, two final settling tanks of 36 cu m each and a facility to chlorinate the waste stream before it is discharged to a river. An 81 cu m aerobic digester and a 50 cu m sludge thickener are provided. Subsequent solids disposal is to a landfill.

Waste samples were taken by RFW Co. from September 10, 1974, to September 13, 1974. Composite samples were taken on each of the four days from the research areas, the total process and sanitary waste flow into the treatment plant. The treatment plant effluent was sampled for one day.

The average total wastewater flow was 220 cu m/day, including 64 cu m/day average from the research facilities. Average analytical results were as follows:

	Influent		Effluent	
	mg/l	kg/day	mg/l	% removal
Total Wastewater				
FLOW*		220*		
BOD	364	80	3.5	99.0
COD	641	141	28	95.6
SS	41	9.0	22	73
TOC	193	42.5	52	73
Wastewater from Research Facilities			Kg per 100 sq.m	
FLOW*		64*		
BOD	314	20	0.22	
COD	571	39	0.42	
SS	21	1.4	0.015	
TOC	110	7	0.076	

Wastewater from Production Facilities, not including cooling tower and boiler blowdown - by difference

FLOW*		156*
BOD	384	60
COD	655	102
SS	49	7.6
TOC	228	35.5

*Flow in cu m per day

The raw waste loads calculated here show the total loads from the areas without deductions for human wastes.

In addition, the company furnished the following monthly averages of treatment plant effluent for a fifteen-month period.

	BOD mg/l	COD mg/l	TSS mg/l
	8	64	24
	16	72	26
	24	162	36
	14	78	16
	10	26	10
	7	30	26
	10	29	10
	3	136	6
	4	45	12
	9	29	8
	11	19	8
	10	25	12
	12	20	6
	9	44	7
	36	136	24
Average	12.2	61	15.4

Plant 8

The activities of this plant are in subcategory B. The plant produces vaccines and blood fractions for human use. Animals are kept at the facilities for product testing and as a source of serum.

Approximately 100 persons are employed at the facility, working 8 hours per day, 5 days per week.

Wastewaters include tank washings, equipment washings, boiler blowdown, sanitary wastes, process wastes, cage washings and contact cooling water. The combined wastes go to a 2-hectare (5-acre) pond with aerators in the influent end. The pond provides 15 to 30 days aeration. The wastewater then goes into basins where ferric chloride and then a polyelectrolyte are added. Air flotation serves to remove the precipitate, after which the effluent is chlorinated and discharged to a river. Waste sludge is hauled to a landfill.

Samples were taken of the total wastewater in and out of the treatment plant October 9 through 11, 1974. The average total wastewater flow for that period was 473 cu m/day. Average analytical results are presented below.

	Influent		Effluent	Percent
	mg/l	Kg/day	mg/l	Removal
BOD	19	9.1	5.8	70
COD	77	36	48	38
SS	15	7.3	30	
TOC	16	7.6	16	

Deductions were made for sanitary, boiler blowdown, and cooling water, leaving the standard RWL of:

Flow	Parameter	Kg/day
76 cu m/day	BOD	4.75
	COD	14.8
	TSS	0.52
	TOC	1.53

The company provided treatment plant influent and effluent data for 1973 and 1974. The average flow for that period was 719 cu m/day. The average analytical results are:

	Influent		Effluent	% Removal
	mg/l	Kg/day	mg/l	
BOD	46.3	33	7.8	83
COD	118	85	50.5	57
SS	31.6	23	22.2	30

By both sets of data, the wastewaters are of low strength, and the performance of the treatment plant is poor.

Plant 9

The principal activity of this plant is in subcategory A, making a single antibiotic product. There is also a pharmaceutical section which fills and packages 23 products.

Process wastewaters, boiler blowdown, cooling tower blowdown and storm water are pumped to the wastewater treatment facilities, consisting of four lagoons and three "cascade basins." Two of the lagoons with a total volume of 6,000 cu m are equipped with aerators totaling 150 HP. The total flow is said to be 1,570 cu m/day; hence, the aeration period is about four days. Following aeration, the wastewater flows to two more basins with a holding time of 2.8 days, then to three "cascade basins" and finally to a sink hole.

RFW calculated deductions for raw waste loads other than industrial; they amounted to only a few percent of the total, 1.3% in the case of BOD.

The table below shows the available analytical data. The variability and the paucity of the data are such that these results should not be used as a basis for conclusions.

	BOD mg/l	COD mg/l	TOC mg/l	TSS mg/l	NH3/N mg/l	P mg/l
June '74 company data (one day)						
Influent	1151	2119	116	86		2.3
1st lagoon	269	577	142	102		2.2
Sink hole	49	278	132	134	39	3.4
11 October '74 RFW						
Influent	1890	3600	281	785	43	5.0
2nd lagoon	540*					
or	237*	1300				
Effluent		432	144	3	55	5.7
14 October '74 RFW						
Influent	3150	6700	2060	914	55	14.2
2nd lagoon	245		330	286		
Effluent	26	317	155	4	58	7.8
% Removals**	98	91				

* The basic data sheet shows 540.

**These percent removals are obtained for each constituent from the average of all of the influent concentrations and all of the effluent concentrations. "Sink hole" is considered, for this purpose, to be the same as "plant effluent."

Plant 10

The principal product of this plant is vitamin C, but it also manufactures sulfa drugs, and in part packages products in gelatin capsules. It operates 24 hours/day, 5 to 7 days/week.

The wastewater treatment plant provides about 8 hours retention in an equalization pond equipped with two 25-HP floating aerators, followed by an activated sludge process, clarifier and a polishing pond.

Information secured in the RFW studies present a somewhat confusing picture, in that the indicated flow into the treatment plant is twice as great as the flow out and two different figures appear for the daily amount of manufactured product. It is assumed that RFW personnel had adequate reasons for the figures that they used; their computations of raw BOD load/ton of product are accepted and presented below. Deductions were made for sanitary and cooling water. Samples were taken for four days, 9/17/74 through 9/20/74.

	Total waste as measured	Industrial flow, calculated by deducting sanitary & cooling water
Flow, cu m/day	6,820	4,920
BOD, kg/day	8,220	8,180
COD, Kg/day	19,000	18,810
TSS, Kg/day	928	960
TOC, Kg/day	6,410	6,350

Treatment plant data for the same four days gave the following averages:

	Influent	Effluent	% Removal
BOD, mg/l	1,220	47	96
COD, mg/l	2,800	1,350	52
TSS, mg/l	146	122	16
TOC, mg/l	944	606	36

The manufacture of vitamin C, as in this plant, is not a typical subcategory C operation. The raw BOD load per ton of product is relatively low.

Plant 11

Plant 11 is a producer of fine medicinal chemicals in the C subcategory. The production facilities occupy two manufacturing areas, with related administrative facilities. Operations are conducted three shifts/day, seven days/week.

Average daily total waste flow in late 1974 was roughly 1 mgd, with an average raw waste BOD loading of 7,500 lb/day (3,409 kg/day).

Production wastes consist of spent mother liquors, product washings, contact cooling water and other process wastes, all collected in an industrial wastewater system. Sanitary wastes are separately collected and treated in a package activated sludge treatment plant before joining the industrial waste stream and the combined flows are treated in an activated sludge system, discharging effluent to a river. Non-contact cooling water is discharged to the river directly.

Design equalization basin capacity is 12 hours, but actual detention time was 24 hours at 1974 flows. Design detention time in aeration is 12.3 hours, but 1974 flow was one-half the design flow and only three of the six aeration tanks were in use.

Ammonia stripping and cyanide destruction are used on certain process streams before arrival at the treatment plant.

Waste sludge is thickened, vacuum-filtered without digestion and hauled to a landfill.

Company records were available for the period January 1973 to June 1974 showing the following:

	Influent		Effluent		% Removal
	N*	mg/l	N*	mg/l	
BOD	136	894	106	79	91
COD	171	2634	315	398	85
TSS			114	126	

*N = number of samples.

Samples taken 2 October '74 through 5 October '74 were used to determine raw waste loads:

	Kg/day
BOD	7,560
COD	12,500
TSS	950
TOC	6,690

Plant 12

The activities of this plant are in subcategory B. The manufacturing operations produce human blood products, influenza virus vaccine and various unit-dose syringe products.

The only wastewater associated with blood fractionation processes is the washing of equipment, tanks and floors. All waste blood fractions are incinerated and solvents are recovered by distillation and reused.

The only wastewater associated with the sterile injection filling processes is distilled water used for rinsing glass syringe barrels.

All process and sanitary wastewater, boiler blowdown, and 70 to 75% of all contact cooling water is collected by a sewer system that discharges to the municipal sewer. Surface runoff, noncontact cooling water and 25 to 30% of all contact cooling water is discharged directly to the river.

Samples of the total plant effluent were collected for analysis by RFW during the period October 22 through October 24, 1974. The following table shows the results and also the net industrial load as calculated by RFW.

	As Measured Kg/day	Calculated Industrial BOD Load Kg/day
Flow*	89*	
BOD	25.4	20.0
COD	46.3	33.1
SS	5.9	0.45
TOC	9.1	3.6

*Flow is in cu m/day

Plant 14

The activities of this plant are in subcategory E. Included at the facility are small-scale chemical compounding and biological fermentation facilities, animal housing facilities, laboratories, and administrative offices. The pharmaceutical and biological research is directed toward the development and testing of new products. The principal operations are conducted during a single shift, five days per week.

The bulk of the liquid waste generated by the facility consists of cage washings.

All wastewater, cooling water and boiler blowdown are collected by a sewer system and flow to a package activated sludge wastewater treatment plant. A 170 cu m equalization basin is followed by a primary clarifier, an aeration tank, a secondary clarifier and chlorination before discharge to a creek. Dried waste sludge is taken to a landfill.

Composite samples of the influent and effluent were taken by RFW Co. on two days in October, 1974. Average flows and analytical results were as follows:

	Influent	Effluent	Percent Removal
Flow, cu m/day	184		
BOD, mg/l	100	13	87
COD, mg/l	235	32	84
SS, mg/l	238	10	95.8
TOC, mg/l	114	18	84

An estimated deduction for human sources can be made from the above raw waste loads, resulting in the standard industrial raw waste load below:

	kg/day	kg/1000m²
BOD	12.5	1.58
COD	27.3	3.46
SS	37.7	4.77
TOC	14.4	1.83

Flow = 110 cu m/day

The company furnished data on operations of the wastewater treatment plant over a nine month period, January through September, 1974. Data included both influent and effluent levels of BOD, COD and SS. There were 96 influent BOD tests and about 190 tests for the other parameters.

	Influent	Effluent	Percent Removal
Flow, cu m/day	231		
BOD, mg/l	67	1.75	97.4
COD, mg/l	197	18.2	90.8
SS, mg/l	143	5.9	

The average flow during the nine months in 1974 was 231 cu m per day. Deducting for human sources, the average standard raw waste load for that period 9.73 kg/day of BOD and 31.4 kg/day of COD.

Plant 15

This plant is a bulk chemical production facility. Its activities are in subcategory C. The facilities consist of several warehouses, an administration building, a tank farm, and several process buildings. All products are manufactured via batch operations. The manufacturing area operates 24 hours a day, five days a week, while administrative personnel work eight hours a day, five days a week.

Sources of wastewater are varied and include tank washes, barometric condenser water, tank boilouts, cooling water discharges, caustic and acid washes, fume scrubbers, water layer separations, floor and equipment washings and sanitary wastes.

Process and sanitary wastes are collected by separate sewer systems and treated in an activated sludge plant prior to discharge to a river. Caustic and acid wastes are pumped separately to holding tanks. The tank contents are subsequently mixed and neutralized before clarification and discharge to the treatment plant. Stormwater run-off and cooling tower blowdown are discharged into the plant storm sewer system and mixed with treatment plant effluent prior to river discharge.

The treatment plant has an aeration lagoon of 110 cu m volume followed by clarification, neutralization and chlorination. Dewatered sludge is hauled to a landfill.

Twenty-four hour composite samples of the raw process waste and the total effluent from the wastewater treatment plant were obtained by RFW Co. on Oct. 8 and 9, 1974.

	Industrial Stream	Sanitary Stream	Calcu-lated	Effluent Stream	Percent Removal
Flow, cu m/day	129	30	159		
BOD, mg/l	12,200	725	10,000	2,000	80
COD, mg/l	17,900	1,510	14,770	3,680	75
TOC, mg/l	9,170	275	7,480	218*	
TSS, mg/l	326	104	274	47	
NHn-N, mg/l	1,740	13	1,411	1,195	
Phosphate, P	2.1	16	4.7	.24	

*Probably erroneous, in view of COD and BOD data.

The total plant flow, including boiler blowdown and water treatment plant wastes, was 257 cu m/day.

The company furnished data on the process waste flow into the treatment plant and the treatment plant effluent over a period of 17 months in 1973 and 1974. The average analytical results are presented below.

	Process Waste Flow	Treatment Plant Effluent	Percent Removal
COD, mg/l	20,900	14,000	33
SS, mg/l	1,000	359	64

Plant 16

The plant produces flue vaccine, tetanus toxoid and other subcategory B materials and has a research laboratory. (The biologicals are packaged, but this is a normal part of the subcategory B operation). Thus, the plant is classified in the "B" and "E" subcategories. The number of employees is reported to be 200.

Spent eggs, animal bodies and other wastes are incinerated. The wastewater flow, excluding storm flow but including cooling water, amounts to 208 cu m/day. It is treated in an activated sludge plant having an aeration time of about 37 hours. There are two secondary clarifiers in series, each with a detention time of 5 hours. The flow is chlorinated and then goes to a pond providing a detention time of 6 days.

Data submitted by the company show nine pairs of influent-effluent monthly average BOD results obtained in 1974. The BOD results average 106 and 4.4 (96% removal). The average flow, according to the data submitted, is 220 cu m/day. The BOD raw waste load is 22 kg/day.

RFW sampled on October 25, 1974, obtaining in and out BOD values of 23 mg/l and 4 mg/l. These two values cannot be compared, in view of the total detention time of about 8 days in the plant. Furthermore, the RFW data sheet indicates that production was essentially zero on that day. No standard raw waste loads can be calculated.

Plant 17

The operations of this plant are divided into subcategories B, D and E.

The wastewater passes through an equalizing tank, then is treated with hydrogen peroxide (H_2O_2) and oxinite ($NaClO_2$) and discharged to a municipal sewer.

No company data on the wastewater composition have been submitted. RFW Company sampled the total wastewater stream on three days: 29, to 31 Oct., 1974 and sampled streams from the individual subcategories, except on the first day. Flows and analytical data for the principal constituents of interest are shown in the following table.

Sub-category	Flow cu m/day	BOD kg/day	BOD mg/l	COD kg/day	COD mg/l	TOC kg/day	TOC mg/l	TSS kg/day	TSS mg/l	P mg/l	Amm. N mg/l
B	870	751	518	726	834	128	147	28	32	3	.4
D	227	216	950	349	1510	135	595	3	14	22	1.7
E	840	166	198	339	404	64	77	42	50	15	.8
Sum*	1937	833	430	1408	726	327	169	73	38	40	.14

Total* Flow	2645	917	347	1270	650	457	173	161	61	2	.8
Total** Flow	2650	1391	525	2262	854	490	185	88	39	10	.6

* 30 and 31 Oct.
** 29, 30 and 31 Oct.

The flow from the individual sources fall short of accounting for the total flow and raw waste loads measured at the plant.

RFW calculated deductions for sanitary and non-process flows. These deductions amounted to less than 5% of the flows and raw waste loads.

Plant 18

This is a pharmaceutical formulating plant (subcategory D) whose major products are tablet and liquid preparations.

The major sources of wastewater to the treatment plant are tank, floor and equipment washings and sanitary wastes. Boiler blowdown, cooling water and storm runoff are diverted to a holding pond before discharge to a river.

The wastewater treatment plant has a plastic media trickling filter designed for 3200 mg/l of BOD. This is followed by an activated sludge system with an air supply of 5.6 cu m/minute and a design aeration time of 24 hours. The effluent is chlorinated and pumped through a sand filter before discharge to a river.

For determining raw waste loads, company historical data from 1969 (4 days) and RFW data from 1974 (2 days) were used. Averages are presented below:

Flow cu m/day	Parameter	kg/day
104	BOD	104
	COD	224
	TSS	28
	TOC	112

Treatment plant efficiencies are based on RFW data for two days in 1974.

	Influent mg/l	Effluent mg/l	% Removal
BOD	748	59	92
COD	1,670	290	83
TSS	103	2	98
TOC	530	120	77

Plant 19

This is a large plant with activity chiefly in subcategories A, C and D.

Wastewaters from cafeteria, toilets and some research facilities go directly to a municipal sewer. Once-through cooling water returns to a lake.

The process wastewaters are treated in a plant that provides a covered equalization basin holding 2300 cu m and covered activated sludge basins with the same total volume. At current average flow rates the aeration period is approximately 24 hours. Two final clarifiers are designed for overflow rates of 7.33 m/day (180 gallons per sq. ft. per day). This overflow is approximately the present rate.

The plant is well operated. Dissolved oxygen in the aeration tanks, pH, BOD load, mixed liquor suspended solids and temperature are the basis of tuning the plant to obtain the best results. The pH is controlled on the basis of the pH in the aeration tanks. If the temperature of the wastewater exceeds 40°C, as it may in the summer, it is cooled and when necessary steam is added to keep the temperature above 36°C. Management estimates that the aeration period might need to be four times as long at ambient temperatures.

Heretofore the effluent has been discharged to a lake, but it is now going into a municipal sewer.

A relatively high degree of variability has been shown in the performance of this plant. Historical data have shown average performance levels over different periods of time as follows:

Interval	Flow cu m/day	Avg. Inf. BOD, mg/l	% BOD Removal (Range)	Monthly Averages (Average)
June to Dec. 1923	2590	2847	77.4 to 97.8	93.5
Jan. to Dec. 1974	2800	3066	85.0 to 95.2	91.1
Jan. to Apr. 1975	2800	3400	93.3 to 95.4	94.1
May 1975 to April 1976	2350	2919	94.8 to 98.8	96.9

During the 12-month interval from May 1975 to April 1976 the BOD load was 28% less than in the preceding interval. This would contribute in a minor way to the better operation. The company believes that improved facilities and procedures have played an important part. In any case, performance during that interval does not show any trend toward better or poorer results, so it appears that the interval can be used as indicative of the capability of a plant of that type operating under optimal conditions.

Certain other analyses showed the following average values over that period.

	Influent mg/l	Effluent mg/l	% Removal
TOC	2118	304	85.6
TSS		296	

The performance of the plant is highly variable. Ten percent of the time the BOD of the effluent was less than 23 mg/l and 10% of the time it exceeded 160 mg/l. Sometimes the effluent is quite clear, but much of the time it is milky, probably due to non-floccing spirilla or other bacteria that will not settle out. It is characteristic of the activated sludge process that certain kinds of nutrients will produce non-flocculent cultures of this sort. There is little hope that the activated sludge process alone will give clear effluents when treating wastewater from the A and C subcategories.

On Sept. 23 and 24, 1974 RFW measured and sampled the streams from the A and C parts of the plant, as well as the final effluent, with results as follows:

	Fermentations	Chemical Synthesis	Total	Eff.	Percent Removal
Flow, cu m/day	1620	1230	2850		
BOD, mg/l	4215	1650	3110	134	95.7
COD, mg/l	9420	3420	6800	680	90.0
TOC, mg/l	3240	858	2216	292	87
TSS, mg/l	2182	600	1701	210	
TKN, mg/l	245	130	196	60	
Phosphorus, P, mg/l	46	13	32	3.5	

BOD removal, found to be 95.7%, was fairly close to the 12-month average. Therefore the 90% removal of COD is probably at least roughly indicative of the average condition according to Jacobs Engineering personnel reviewing the data.

Plant 20

The activity of this plant is the production of a single antibiotic by fermentation. The active ingredient is in the mycelium, which is sold in bulk and in a dried powdered form.

The wastewater flow in 1974 was reported to be 950 cu m per day. This includes sanitary sewage from septic tanks. The flow is treated in an activated sludge plant having a 4500 cu m aeration basin (and hence an aeration period of 4.8 days), equipped with three 50-HP floating aerators. The flow then goes to a 10-m diameter clarifier, after which it discharges, along with cooling waters, to a river.

The RFW company sampled the wastewater flows on 29 Oct. to 1 Nov., 1974 and obtained the following results:

Date 1974	29 Oct.	30 Oct.	31 Oct.	1 Nov.
Flow cu m/day	927	946	946	965
BOD, mg/l				
Infl.	750	3,700	310	770
Effl.	90	110	20	222
COD, mg/l				
Infl.	1,440	14,160	434	1,490
Effl.	499	1,210	2,590	887

TOC, mg/l				
Infl.	530	5,000	121	440
Effl.	201	225	130	315
TSS, mg/l	282	386	38	812
Ammonium, N mg/l	10	93	5	60
Phosphate, P mg/l	7	40	0	12

In view of the long retention period in the treatment plant (about 5 days) and the large variations of the influent, the samples cannot be considered as even approximately matched. The results are of very little value for calculating either standard RWL's or treatment plant efficiency.

Plant 21

Fermentations are a major source of high-strength wastewaters at this plant. Chemical systhesis facilities manufacture benzoic and fumaric acids on a large scale, but do not produce a large wastewater load. Briefly, the process wastes plus sanitary wastes pass through these units:

a. Primary earthen clarifier, 260 cu m.

b. Two aeration ponds, equipped to operate either in parallel or in series, with a total volume of 28,000 cu m. Each pond is equipped with five 75-hp. floating aerators.

c. Secondary earthen clarifier, 400 cu m sludge is in part returned to the aeration basins, thus making this an activated sludge process.

d. Two clarigesters, providing additional sedimentation.

e. Two trickling filters with rock media, 240 cu m total. These are used as nitrifying units, as the BOD removal capacity is not critical.

f. Plastic media filter with 1160 cu m of media.

g. Final clarifier, 280 cu m.

h. Stabilization pond, 3 ha., 38,000 cu m equipped with six 20 hp aerators. The aerators were not being used at the time of our visits on 1 and 2 April 1976 and reportedly are used only as a backup system under present operating conditions.

i. Final polishing pond, 14 ha., 170,000 cu m.

j. Chlorination in a small "retention basin."

k. Discharge to a creek, where it mixes slightly polluted cooling water and surface drainage from the plant area. The sampling points designated, "Sidestream Dam" or "Powerline," represent the combined discharge. Except for storm periods, this flow constitutes the full flow of this creek.

Sludge removed in the treatment works goes to an aerobic digestion basin where it is aerated by three to five 75-hp. surface aerators. Part of it goes to a 16 ha. stabilization pond from which there is no overflow. The rest of the sludge is spread on agricultural land owned by the company.

The flow through the treatment plant is about 4600 cu m per day. Hence, the detention time is 6 days in the activated sludge basins and about 44 days in the ponds that follow the trickling filters. The other flow (chiefly the 1100 cooling-water system) amounts to about 10,000 cu m/day.

The company reports that in 1975 the average reduction of BOD at the end of the activated sludge process was 93.1%; after the trickling filters it was 96.1%; after the 7.5 acre polishing pond, it was 98% and after the final pond, it was 99+%.

The total power needs of the treatment plant were estimated by plant personnel to be 1400 to 1500 hp (as cited by Struzeski).

Sludge disposal, by using it agriculturally on company-owned land, is an interesting operation. A similar project is described in Water and Sewage Works, January 1976. With cropping, the amount that can be spread is 38,000 gal. per acre per year. At 3-1/2% to 4% solids, this amounts to about 12,000 lbs. of solids per acre, (13,500 kg/ha) containing 1250 lbs of N per acre, (1400 kg/ha), nearly all in an organic form. The nitrogen content may limit the rate of application because of problems that may be caused by nitrate in the ground water. At an application rate of 38,000 gal/acre/year, about 750 acres would be needed to receive all of the sludge. Roughly half of the sludge produced is applied to the land. It is hoped that the sludge can be commercialized. This will necessitate delivering the sludge at greater distances. Because of the hauling costs, it will be necessary to reduce the water content.

The plant also has a small filling and packaging operation and a research laboratory. It was not possible to sample these flows separately nor to determine the total flow from them. There is also, at a distance of about two miles, a "Research Farm" where large animals are kept for experiments in feeding. A very small wastewater flow is brought to the manufacturing plant by pipeline. A surcharged manhole on the line contained what appeared to be unpolluted water. It was not sampled. The methods of manure disposal applied generally on farms are suitable here.

Plant 22

The activities of this plant are in the A and C subcategories.

The treatment plant for the process wastewaters plus sanitary wastewaters has these principal units:

1. Equalizing basin, 1200 cu m.
2. Neutralization basin.
3. Sedimentation basin, 20 m diameter.
4. Plastic media trickling filter, 1680 cu m.
5. Activated sludge, providing an aeration period of 4 hours.
6. Floatation for separating the sludge.
7. Two trickling filters in parallel, totaling 4,200 cu m of media.
8. Two final clarifiers 12 m in diameter.
9. Discharge to a watercourse.

At one time the company incinerated the liquid wastes, but discontinued the practice because of high cost.

Waste sludge is passed over Sweecc screens, then centrifuged and hauled to a landfill, but the company plans to place a sludge incinerator in operation scon.

The company has submitted data relative to wastewater treatment for 1974 and 1975. The year 1975 is used for appraising performance. Production was reduced or discontinued during all or part of five weeks in the summer and a week at the end of the year. Those weeks are deleted from the record used for appraising performance.

Flow thru the wastewater treatment plant averaged 4707 cu m per day. A cooling water stream of 21,000 cu m per day joins the process effluent before final discharge. BOD tests were run weekly and COD tests daily. Suspended solids (TSS) tests were made daily, but only in the effluent after admixture of cooling water. A hypothetical calculation of suspended solid in the treatment plant effluent was made on the assumption of no suspended solids in the cooling water. These results must be looked upon only as indication of the largest amounts that might have been present in the effluents.

Tests for ammonium, reported as N, were also made daily and tests for total phosphorus three times a week. These tests were on the total plant effluent including the cooling water. As in the case of the TSS determinations, these results have been converted to hypothetical concentrations on the assumption of no N or P in the cooling water.

	1974	1975	21-month average
Flow, cu m/day	5070	4730	4875
Influent COD, mg/l	5330	4980	5130
Influent BOD, mg/l	2660	2420	2520
COD reduction, %	75.3*	76.0	75.8
BOD reduction, %	93.4*	93.1	93.2
Ammonia in effluent, as N, mg/l		33	
Total phosphorus as P, mg/l		10.1	

* Except first 3 months, when plant performance was poor.

Samples were taken by Jacobs Engineering Co. on 23 and 24 March and 1 April, 1976, with results as follows:

	Wastewater from	
	Fermentation Plant	Chemical Plant
Flow, cu m/day	1320	303
BOD, mg/l	1820	7700
COD, mg/l	4670	16000
TOC, mg/l	1120	6080
TSS, mg/l	675	555

Treatment plant effluent samples were obtained on only one day, and showed BOD and COD reductions of 94% and 74%.

Plant 23

The major facilities consist of vaccine and serum production area, filling and packaging of various synthetic organics, virology and control laboratories, bleeding barn, barn for horses, chicken house, softener, small cooling tower, maintenance shop and offices. The plant has a large distilled water unit but no demineralizer. The waste treatment plant is located a few hundred yards away. Thus, the plant can be subcategorized as belonging to subcategories B, D and E.

The subcategory D activities are not large-scale operations, since the daily output of product is less than 1 kg per employee. The raw waste load arises largely from operations of the B subcategory. Wastes from large animals apparently are not included in the wastewater flows.

All the wastewaters are collected in a sump and pumped to the treatment plant. The plant includes a 150 cu m equalizing basin, two activated sludge aeration tanks with a total volume of 254 cu m, a 117 cu m clarifier and a chlorination tank.

The company supplied reports of wastewater analyses for 1974 and 1975. The PJB laboratory of Jacobs Engineering Co. analyzed samples taken on 4 and 5 May, 1976. The average results for the company's 1975 data and the PJB data are shown below:

	Company data, weekly tests for 1975	PJB data, two days in 1976
Flow, cu m/day	345	332
BOD, influent, mg/l	21.2*	11
effluent, mg/l	1.4	2
Percent removal	93.4%	
COD, influent, mg/l	105	98
effluent, mg/l	63	67
Percent removal	40%	32%
TSS, effluent, mg/l	18	

*In three of the BOD tests all of the oxygen was depleted. In two cases BOD results were estimated on the basis on the COD test, BOD averaging 0.24 of the COD in the raw wastewater of this plant. The third was estimated as being as great as the highest BOD test reported.

**The PJB data are insufficient for reliable percent-removal data, especially in the case of BOD.

Plant 24

The activities in this plant are in subcategories D and E. The major facilities consist of compounding, filling, packaging, a small pilot plant, quality control laboratories, offices, warehouse and utilities. A separate small building contains the toxicology laboratories. The plant operates essentially on a five-day, one-shift schedule.

Wastewater from floor and equipment washing in the toxicology building joins waste flows from human service facilities in what is called the sanitary waste line. All manufacturing area floor washings, spills, equipment cleanings and cooling tower blowdown are run through the industrial wastewater line. The two flows join just before entering the treatment plant.

The treatment plant includes a 26 cu meter skimming tank, two 296 cu meter equalization tanks receiving 15 cu meters/min of air, two 26 cu meter "stabilizers" (?), four activated sludge aeration tanks totaling 212 cu meters and two 26 cu meter clarifiers. Aerobic digestion and dewatering of the sludge is provided.

The wastewater flow is quite well equalized over the 7-day week, being only 11% lower on non-working days. The calculated average aeration period in the activated sludge tank is 16 hours. The equalization tanks provide in effect a rather long but variable period of pre-aeration.

The company furnished data on operations of the wastewater treatment plant over a two-year period ending with March 1976. The data for the 12-month period from April 1975 to March 1976 is used. Tests were made once a week for influent and effluent BOD and TSS. Effluent COD determinations were made on each of the 245 working days.

Average results by months were as follows:

Month	Average Flow cu meters/day	Concentration, mg/l			
		BOD Eff	COD Eff	TSS Eff	BOD Inf
April '75	297	12.0	40	17	206
May '75	338	6.5	40	21	131
June '75	359	11.2	42	20	158
July '75	348	12.4	40	26	140
August '75	389	10.2	49	23	152
September '75	399	19.3	68	24	176
October '75	355	10.1	57	22	199
November '75	338	14.4	53	39	213
December '75	267	9.4	69	36	257
January '76	298	18.3	80	54	279
February '76	288	14.8	88	34	224
March '76	272	8.8	70	26	204
	329	12.3	58.0	28.5	195

The flow shown in the above table is the average for the working days. The concentrations shown are the arithmetical averages of the concentrations as determined, not the weighted averages that result from dividing average load by average flow.

Samples were taken in April 1976 and analyzed cooperatively by the company and the PJB laboratory of Jacobs Engineering Co. with results as shown in the following table.

Standard factors for calculating the BOD contribution from the human service facilities would indicate that about half of the raw BOD load was from that source. However, the factor used for that calculation, 0.023 kg per employee, may be too large.

ANALYSES OF COMPOSITE SAMPLES TAKEN IN APRIL 1976

Flows: 28 - 29 April 273 cu meters
29 - 30 April 307 cu meters

Date (April)			Industrial Waste mg/l	Industrial Waste kg/day	Mixed Influent mg/l	Effluent (chlorinated) mg/l	% Removal
28-29	BOD	PJB *	134	36.6	76	5	
29-30		PJB	74	22.7	67	4	
28-29		Company	162	44.2	126	16	
Average			123	34.4	90	8	91
28-29	COD	PJB	306	83.6	320	93	
29-30		PJB	216	66.3	304	93	
28-29		Company	315	86.0	311	72	
29-30		Company	215	66.0	279	68	
Average			263	75.5	304	82	73
28-29	TSS	PJB	25	6.8	60	24	
29-30		PJB	20	6.1	59	26	
28-29		Company				32	
29-30		Company				34	
Average			22	6.4	60	29	52

*PJB laboratory at Jacobs Engineering Co.

Plant 25

Production Operations: Fermentation and subsequent refining, sterile bulk manufacturing, fine organic chemicals and antibiotic production, chemical development pilot plant and laboratories, quality control labs, some packaging, filling and compounding operations.

Ultimate discharge is to municipal sewers, but the process wastes from subcategories A and C operations are pretreated to reduce the BOD. Sanitary wastes, including most of the wastes from subcategories D and E operations, go to the sewer directly.

The pretreatment plant has four aeration tanks totaling 5,200 cu m, but about 10% of the volume is baffled off to provide sedimentation. A dilute sludge is pumped from this compartment partly to return to the aeration basin and partly to clarifiers or thickeners. The sludge, after centrifuging, is hauled to a landfill. The flow through the treatment plant averages 1,000 cu m per day. The aeration period is 3-1/2 days.

The company has submitted records of effluent analyses for 1974, 1975 and the first three months of 1976. Using the 12-month period from April 1975 to March 1976, the average flows and concentrations of wastewater discharged to the sewer were as shown below:

Flow, cu m/day	1500	
BOD, mg/l	252	
COD, mg/l	1487	
TSS, mg/l	927	(20.0% Ash)
TS, mg/l	3234	
Cl_2 demand, mg/l	78	

Samples were taken for anlysis by Jacobs Engineering personnel on 27 and 28 April, 1976, with results as shown on the laboratory report sheets. From the analyses and information on flows as submitted by the company, the following table has been constructed to show the waste loads carried by different streams. (The total flow during the May sampling was lower than the 12-month average.)

Plant 25

Analytical Data by PJB Laboratory of Jacobs Engineering Co.

Stream	Filt. Residue (D.S.) mg/l	Non-Filt. Residue (S.S) mg/l	BOD5 mg/l	COD mg/l	TOC mg/l
Wastewater from fermentation 4/26/76, comp.	31,480	436	22,800	34,800	14,400
Wastewater from fermentation plus solvent recovery, 4/28/76 comp.	25,400	420	13,400	76,300	10,800
Bulk chemical waste-water, 4/27/76, grab	558	21	1,020	15,600	3,200
Bulk chemical plus development waste-water 4/27/76, grab	17,200	44		2,480	690
Sterile bulk chemical mfg., 4/27/76, grab	958	41	603	1,920	450
Equalization basin in-fluent 4/28/76, comp.	4,708	862	2,320	6,430	1,600
Equalization basin effu-ent 4/27/76, comp.	6,172	858	3,830	7,740	1,900
Effluent pretreated for discharge to sewer, 4/27/76, comp.	4,264	1,282	208	2,640	820
Effluent pretreated for discharge to sewer, 4/28/76, comp.	4,264	1,404	353	5,490	1,700
Total plant effluent grab	2,550	744	197	2,560	1,620

According to this Table 25, it would appear that BOD5 and COD removals from equalization basin effluent to treatment plant effluent ("equalization basin effluent" to "effluent pretreated for discharge to sewer") were 93% and 48% respectively.

Plant 26

This plant conducts operations in subcategories A, B, C, D and E. Except for sanitary wastes, all flows are intermingled. It is not possible to obtain separate samples for the different subcategories.

In the wastewater treatment plant, the total flow, including sanitary flows, is first treated with Magnifloc at a dosage rate of about 1 mg/l and then goes to an 18 m diameter clariflocculator. Secondary treatment is provided by activated sludge using refined oxygen produced at the site, in an aeration tank of 3000 cu m capacity. Then it goes to three clarifiers in parallel and a fourth one in series, each one 12 m in diameter. The effluent is chlorinated and discharged to a municipal system.

Company data have been supplied in the form of monthly averages for the period from Jan. 1974 to March 1976. During the first year, some of the loads, both influent and effluent, have been considerably higher than at any time since. They are still highly erratic, but there has not been a conspicuous trend since then. It is reasonable to use the twelve-month period from April 1975 to March 1976 as a basis for appraising treatment plant performance. For this period the following average conditions prevailed:

			1975 data	
	Flow cu m/day	Influent mg/l	Effluent mg/l	Percent Removal
	4340			
BOD		1239	93	92.5
TSS		1135	177	83.7

On March 25, 1976, personnel of Jacobs Engineering Co. in cooperation with plant personnel took 24-hour composite samples and on March 26, they took composites from 8 am to 9 pm. The samples were split and analyzed by the laboratory of the plant as well as the PJB laboratory of Jacobs Engineering. (Subsamples for TOC were sent to another laboratory.) Except for BOD, the differences between the results by the two laboratories are in a tolerable range.

The 24-hour and the 12-hour composites did not indicate any consistent tendency for the 12-hour to be higher or lower than the 24-hour composite. Weighted averages were taken in proportion to the times. Average values of the principal parameters of wastewater load are as follows:

	Influent	Effluent	Percent Removal
BOD, mg/l	1150	48	96
COD, mg/l	2536	211	92
TOC, mg/l	373	27* 120*	
SS, mg/l	1590	153	

*Doubtful results

SECTION V

WASTE CHARACTERIZATION

General

This section is intended to describe and identify the water usage and wastewater flows in the pharmaceutical manufacturing point source category. After developing an understanding of the fundamental production methods and their inter-relationships in each subcategory, a determination was made of the best method of characterizing each manufacturer's discharges which would enhance the interpretation of the manufacturer's wastewater profile. If unit raw waste loads could be developed for each production process within a segment, then the current effluent wastewater profile could be obtained by simply adding the components. To forecast future profiles it would be a routine matter of projecting the types and sizes of future manufacturing operations and adding the associated wastewater loads to determine what the new wastewater load would be.

Pharmaceutical Manufacturing

Plants in the pharmaceutical manufacturing point source category operate continuously throughout the year. Their processes are characterized largely by batch operations, which have significant variations in pollutional characteristics during any typical operating period. However, some continuous unit operations are used in the fermentation and chemical synthesis subcategories. Batch operations refer to those processes that utilize reactors on a fill-and-draw basis. The reactor is charged with a batch of raw materials, and at the conclusion of the reaction, the vessel is emptied, cleaned, and charged again with raw materials. In a batch operation, the flow of raw material into a reactor and the flow of product from the reactor are intermittent. In a continuous operation, the flow of raw materials into a reactor and the flow of product from the reactor are continuous. Hybrid operations derived from these two types of operation are called semi-continuous.

The major sources of process wastewaters in the pharmaceutical manufacturing point source category include product washings, product purification and separation, fermentation processes, concentration and drying procedures, equipment washdowns, barometric condensers and pump-seal waters. Wastewaters from this point source category can be characterized as having high concentrations of BOD5, COD, TSS and volatile organics. Wastewaters from some wet chemical syntheses may contain heavy metals (Fe, Cu, Ni, Ag) or cyanide and may have anti-bacterial constituents which can exert a toxic effect on biological waste treatment processes. Considerations significant to the design of treatment works are the highly variable BOD5 loadings, high chlorine demand, presence of surface-active agents, the possibility of nutrient deficiency and the possibility of potentially toxic substances.

Subcategory A - Fermentation Products

Fermentation is an important production process in the pharmaceutical manufacturing industry. Liquid wastes from a fermentation plant can be classified as (1) strong fermentation beers, (2) inorganic solids, such as diatomaceous earth, which are utilized as a product or an aid to the filtration process, (3) floor and equipment wash waters, (4) chemical wastes such as solvent solutions used in extraction processes and (5) barometric condenser water resulting from solids and volatile gases being mixed with condenser water.

The most troublesome waste of the fermentation process is spent beer. The beer is the fermented broth from which the valuable fraction, antibiotic or steroid, has been extracted, usually through the use of a solvent. Spent beer contains the residual food materials such as sugars, starches and vegetable oils not consumed in the fermentation process. Spent beer contains a large amount of organic material, protein and other nutrients. The spent beer frequently contains high amounts of nitrogen, phosphate and other growth factors as well as salts like sodium chloride and sodium sulfate.

Methods for treating the liquid fermentation waste are generally biological in nature. Although fermentation wastes, even in a highly concentrated form, can be satisfactorily treated by biological systems, it is much better and less likely to upset the system if these wastes are first diluted to some degree by addition of other waste streams. One such recommended method is to combine fermentation wastes with large volumes of sanitary effluents. No further nitrogen, phosphorus or trace elements are generally needed to carry out a satisfactory biological reduction of the contaminants in the combined wastes. Fermentation wastes are characterized by high BOD5, COD and TSS concentration and pH values generally ranging between 4 and 8.

Subcategory B - Biological and Natural Extraction Products

The two major production processes utilized to manufacture biological products are blood fractionation and vaccine production. The primary sources of wastewaters in blood fractionation processes are spent solvents, waste plasma fraction and equipment (reactor) wash waters. Generally, the spent solvents are recovered or incinerated with the waste plasma fraction. The primary sources of wastewater generated during vaccine production are spent media broth, spent eggs, glassware and vessel washings and bad batches of production seed and/or final product. The spent media broth and spent egg wastes are usually incinerated, while the washwater wastes are sewered. Natural extractions production includes the processing of bulk botanical drugs and herbs. The primary wastewater sources include floor washings, residues, equipment and vessel wash waters and spills. Whenever possible, bad batches are recycled; if this is not feasible, the bad batches are discharged to the plant process sewer system. Solid wastes, such as spent plant tissue, are usually landfilled or incinerated. The wastewaters from these production processes are characterized by low BOD5 and COD concentrations and pH values between 6 and 8.

Subcategory C - Chemical Synthesis Products

The effluent from the chemical synthesis segment of the pharmaceutical manufacturing industry probably is the most difficult to treat compared with the others, because of the many batch type operations and chemical reactions, including nitration, amination, halogenation, sulfonation, alkylation, etc. The processing may generate wastes containing high COD, acids, bases, cyanides, refractory organics, suspended and dissolved solids, and many other specific contaminants. In some instances, process solutions and vessel washwater may also contain residual organic solvents. Thus, it may be necessary to equalize or chemically treat a process wastewater before it is acceptable for discharge to a municipal or on-site conventional biological treatment facility.

Wastewaters from the production of fine chemicals are characterized by high BOD5 and suspended solids concentrations and pH variations from 1 to 11. Major wastewater sources from these chemical plants include process wastes (filtrates, centrates, spent solvents, etc.), floor and equipment wash waters, ejector condensate, spills, wet scrubber spent waters and pump seal water. Some wastewaters from chemical manufacturing plants are not always compatible with biological waste treatment and although it is sometimes possible to acclimate bacteria to various chemicals, there may be instances where certain chemical wastes are too concentrated or too toxic to make this feasible.

Subcategory D - Mixing/Compounding and Formulation

Pharmaceutical manufacturing represents all the various operations that are involved in producing a packaged product suitable for administering as a finished, usable drug. The majority of pharmaceutical manufacturing firms are compounders, special processors, formulators and product specialists. Their primary objective is to convert the desired prescription to tablets, pills, lozenges, powders, capsules, extracts, emulsions, solutions, syrups, parenterals, suspensions, tinctures, ointments, aerosols, suppositories and other miscellaneous consumable forms. These operations can be described as labor intensive and low in waste production. In general, none of the unit operations utilized in manufacturing a drug (i.e., mixing, drying, tableting, capsulating, packaging, etc.) generates wastewater because none of them uses water in any way that would cause a water pollution problem. The primary use of water in the actual manufacturing processes is for cooling water in chilling units. The major sources of wastewater from a pharmaceutical manufacturing plant are: floor and equipment wash waters; wet scrubbers; inadvertent raw material, intermediate, or product spills; and laboratories. The use of water to clean out mixing tanks can flush materials of unusual quantity and concentration into the plant sewer system. The washouts from recipe kettles, which are used to prepare the master batches of the pharmaceutical compounds, may contain inorganic salts, sugars, syrup, etc. Dust fumes and scrubbers used in connection with building ventilation systems or, more directly, on dust and fume generating equipment, can be another source of wastewater depending on the characteristics of the material being removed from the air stream.

The current manufacturing practices established by industry and codified by the FDA have insured a number of safeguards with regard to several of these wastewater sources:

1. Tableting, pill, encapsulating and powder preparation areas are segregated, with air control to remove air-borne particles through adequate recovery systems.

2. Bulk chemical preparation areas involving aqueous solutions are generally curbed and guttered so that spills and washdowns can be directed to the proper treatment system.

3. Generally, pharmaceutical operations are under-roof; thus, storm water contamination does not present a problem.

4. Generally, pharmaceutical operations utilize scrubbing systems on any vacuum or vent air control systems. Thus, seal and scrubber water can be discharged to the proper drain system for appropriate treatment.

Pharmaceutical plants generate wastewater effluents similar in characteristics to domestic sewage and readily treatable in a biological treatment system. The wastewaters from a pharmaceutical manufacturing plant are generally characterized by low BOD and COD concentrations and by a pH from 6 to 8.

Subcategory E - Research

Generally, quantities of materials being discharged by research operations are relatively small when compared with the volumes generated by production facilities. However, the problem cannot be measured entirely by volume of material going to the sewer. Research operations are frequently erratic as to quantity, quality and time schedule when wastewater discharging occurs. The most common problem is that of flammable solvents, especially volatile solvents such as ethyl ether, that can cause explosions and fires. The major wastewater sources are vessel and equipment washings, animal cage wash water, and laboratory-scale production units. The wastewaters are generally characterized by BOD_5 and COD concentrations similar to domestic sewage and by pH values between 6 and 8.

Factors Affecting Wastewater Characteristics

The characteristics of the wastewater generated by a plant in the pharmaceutical industry depend a great deal on various in-plant production procedures. Specifications and standards in "The Good Manufacturing Practices Regulations" place severe restrictions on the ability to reuse and recycle process effluents because of cross-product contamination considerations. However, some of the industrial in-plant pollution abatement techniques which are

TABLE V - 1a

Raw Waste Loads

Subcategory and Plant		Production kkg/day	Flow cu m/day	BOD kg/day	BOD mg/l	COD kg/day	COD mg/l	TSS mg/l
A	01	3.0	*	3750	*	9330	*	*
	04	2.21	1040	4520	4350	7300	7020	610
	09	0.64	2060	6490	3150	13,800	6700	914
	19	2.4	1620	6830	4215	15,300	9420	2180
	20	3.3	946	1305	1380	4140	4380	1860
	21	2.0	4600	6120	1330	15,000	3260	360
	22	1.84	1320	2560	1940	6420	4860	765
	Average	2.2	1930	4510	2730	10,200	5940	1110
B	08	0.06	473	9.1	19	36	77	15
	12	0.15	89	24	271	45	506	64
	17	1.94	870	450	520	726	834	32
	23	0.16	332	3.6	11	32	98	
	Average	0.58	441	122	205	210	379	37
C	04	32.9	4150	2330	561	9340	2250	773
	10	31.6	6820	8220	1220	19,000	2800	146
	11	8.8	3420	7560	2220	12,500	3670	281
	15	1.11	159	1590	10,000	2350	14,800	274
	19	11.3	1230	2030	1650	4210	3420	600
	22	5.01	303	2720	8960	5150	17,000	—
	Average	15.1	2680	4080	4100	8760	7320	415

*Non-typical values since waste is incinerated

TABLE V - 1b

Raw Waste Loads

Subcategory and Plant		Production kkg/day	Flow cu m/day	BOD kg/day	BOD mg/1	COD kg/day	COD mg/1	TSS mg/1
D	03	30.2	1530	272	178	636	416	49
	05	8.99	156	60	384	102	670	49
	17	24.8	227	216	950	349	1510	14
	18	17.6	284	212	748	473	1670	103
	24	13.6[1]	290	26	90	88	304	60
	Average	19.0	497	157	470	330	914	55
E	05	92[2]	64	20	314	39	571	21
	14	79[2]	184	18.4	100	43.1	235	238
	17	375[2]	840	166	198	339	404	50
	Average	182	363	68.1	204	140	403	103
AC	25[3]	0.58	1015	806	795	5370	5300	83
	26	9.4	4160[4]	4780	1150	10,600	2540	1590

[1] Active ingredients = 1.6

[2] Floor area x 100 m^2

[3] A and C RWL can be separated but production cannot

[4] Assumed average flow

used and can significantly influence a plant's wastewater characteristics are discussed below:

1. Solvent recovery and recycle are normally practiced in both the chemical synthesis and fermentation segments of the industry. Certain products require a high purity solvent in order to achieve the required extraction efficiency. This increases the incentive for making the recovery process highly efficient. Ammonia recovery and reuse are employed in some cases.

2. Incineration is a common unit operation in the pharmaceutical manufacturing industry. Some solvent streams which cannot be recovered economically are incinerated. Incineration is also used to dispose of such items as "still bottoms" from solvent recovery units, research animals, sludges and waste materials from biological products manufacturing.

3. Dry-vacuum cleaning units are used extensively in pharmaceutical manufacturing plants. In this practice, a potential source of significant wastewater flows is removed, in exchange for a solids-handling problem which has significantly less adverse environmental impact.

4. Chemical synthesis plants also employ various pretreatment operations for cyanide destruction and the removal of heavy metals from the wastewaters generated by certain unit operations. This practice improves the biological treatability of the plant's wastewater and reduces the potential problem of metals or cyanide in the final effluent from the wastewater treatment plant.

Although the study survey teams did observe some of these in-plant measures, information provided by the individual plants concerning their operation was minimal and sampling around these units was not allowed. For these reasons, it was not possible to evaluate the efficiencies of such units and determine their effectiveness to reduce raw waste loads.

Raw waste loads (RWLs) were computed for each of the plants visited during the study survey period. Only contact process wastewaters were used in calculating these loading values. The noncontact streams which were segregated from the contact process wastewater flows and were not included in the raw waste load figures include the following:

1. Domestic sewage wastewaters.
2. Boiler and cooling tower blowdowns or once-through cooling water.
3. Chemical regenerants from boiler and process feed water preparation.
4. Storm water runoff from nonprocess plant areas, e.g., tank farms.

Five major parameters were considered:

1. BOD_5 raw waste loading (expressed as kg BOD_5/day)
2. COD raw waste loading (expressed as kg COD/day)
3. TSS raw waste loading (expressed as kg TSS/day)
4. TOC raw waste loading (expressed as kg TOC/day)
5. Contact process wastewater flow loading (expressed as cubic meters (cu m)/day)

The RWL figures for subcategory E are expressed as cubic meters or kilograms per 1,000 square meters of floor area.

Development of the raw waste loads (RWL) was accomplished in stepwise fashion from the data obtained in the field. The RWL data relating to individual manufacturing processes were grouped according to the subcategory in which the processes were assigned. The RWL figures computed for the plants surveyed are shown by subcategory in Table V-1. Information regarding raw waste loads and wastewater treatment plant performance in the pharmaceutical industry was gained by visiting 23 plants. With the generous cooperation of the companies, various waste streams were sampled for analysis (See supplement B). The companies supplied confidential information regarding production, as well as treatment plant layouts, number of employees, flows, historical data on performance of the treatment facilities, etc.

The samples obtained in conjunction with the inspection tours generally represent conditions on only one to three days and hence are less reliable than the historical data of the companies, but they are used if other information is not available. Furthermore, those samples were generally analyzed for several constituents in addition to the principal parameters of waste load, and they also serve to indicate that the companies' analyses and the survey's results are measuring essentially the same characteristics.

Raw waste loads were calculated from what appeared to be the most reliable available data. The estimated loads coming from human accommodations (toilets, cafeterias) were rarely available for separate sampling. For the purpose of correcting the raw waste loads to reflect the industrial loads, the human wastes were estimated on the following basis:

Parameter	Per capita per day
Flow	0.11 cu m (30 gallons)
BOD	0.023 kg (0.05 lbs.)
COD	0.056 kg (0.125 lbs.)
Suspended Solids	0.023 kg (0.05 lbs.)

Corrections were made in subcategories B, D and E, but in the A and C subcategories the human loads are insignificant, being less than 1% of the total.

For subcategories A, B, C, D and E, the RWL values were determined by averaging the RWL values computed for the plants in each subcategory. These RWL values are shown in Table V-1. RWL values for TSS were not developed for any of the subcategories; instead, allowable TSS effluent concentrations are proposed. This approach was taken because of the fact that suspended solids will be developed in any biological wastewater treatment system and it is, therefore, more logical to establish an allowable TSS effluent concentration.

As expected, plants falling into subcategories A and C generate wastewaters with the highest pollutant concentrations. In subcategory A, these high levels are primarily due to spent solvents used in extraction processes and sewered fermentation beers. In subcategory C, a myriad of organic chemicals are used as intermediates in the production of fine chemicals and contribute significant pollutant loads to plant wastewater effluents.

Most of the formulating and packaging of pharmaceutical products is done in plants other than those that are producing the basic active ingredients, but there are some plants which do carry out both functions. For the purpose of calculating the standard raw waste load, such plants should be treated as though they were two. The basic ingredient would be counted once as the product of the subcategory A or subcategory C process producing it and again as a product of the subcategory D process of preparing it for sale. This does not apply to plants of the B category, where vaccines and antitoxins are invariably produced in a form ready for market.

TABLE V-2

Comparison of Raw Waste Load Data
Pharmaceutical Industry

Parameter	Units	Range of Values				
		Subcategory A	Subcategory B	Subcategory C	Subcategory D	Subcategory E
Flow	cu m/day	946-4600	89-870	159-6820	156-1530	64-840
BOD	kg/day	1305-6830	3.6-450	1590-8220	26-272	18-166
	mg/l	1330-4350	11-520	561-10,000	90-950	
COD	kg/day	4140-15,300	32-726	2350-19,000	88-636	39-339
	mg/l	3260-9420	77-834	2250-17,000	304-1670	
TSS	mg/l	360-2180	15-64	146-773	14-103	21-238
COD/BOD		1.62-3.17	1.61-8.89	1.48-4.01	1.62-3.38	1.82-2.35
BOD/TSS		0.74-7.13	1.27-16.2	0.72-36.5	1.5-67.8	0.42-15.0

TABLE V-3
SUMMARY OF RAW WASTE LOADS

Sub. Cat.	Contaminants of Interest	Flow cu m/day	Raw Waste Load (RWL) BOD_5 kg/day	BOD_5 mg/l	COD kg/day	COD mg/l	TSS mg/l
A	BOD_5, COD, TSS NH_3-N, Total-N, PO_4	1930	4510	2730	10,200	5940	1110
B	BOD_5, COD, TSS NH_3-N, Total-N, PO_4	441	122	205	210	379	37
C	BOD_5, COD, TSS NH_3-N, Total-N, Hg, PO_4	2680	4080	4100	8760	7320	415
D	BOD_5, COD, TSS NH_3-N, Total-N, PO_4, Hg.	497	157	470	330	914	55
E	BOD_5, COD, TSS NH_3-N, Total-N, PO_4, Hg.	363	68.1	204	140	403	103

There are also a few plants that produce an antibiotic by fermentation and then molecularly alter it by processes similar to those used for chemical synthesis. The material should be counted once as a product of subcategory A and again when it emerges in its final form as a product of subcategory C.

Table V-2 presents a summary of RWL parameter ranges for each subcategory, as well as several ratios calculated to determine whether correlations existed between any of the parameters. From this table, it can be seen that the pollutant raw waste loadings within each subcategory were fairly consistent, although the raw waste loads varied considerably from subcategory to subcategory. This would verify the subcategorization selected for the pharmaceutical industry. Also, although the COD/BOD5 and BOD5/TSS ratios varied widely within each subcategory as well as from subcategory to subcategory, the BOD5/TOC ratios within each subcategory were generally close and fairly consistent from subcategory to subcategory.

Some thought has been given to the establishment of a subcategory E2, the farm type of research station in which large animals and poultry are kept. In some cases the disposal of animal manures follows the similar operations on farms generally. In at least one case, animals are kept on slotted floors, with the excreta washed into a sump and being treated by biological oxidation.

TABLE V-4a - RAW WASTE LOADS

(kg/day)

Subcategory and Plant		TDS	TKN	NO_3-N	TOTAL P	OIL & GREASE	Cl	SO_4	HARDNESS	Ca
A	01	2080	516	0.003	60.6	------	------	------	------	------
	04	4400	213	------	20.0	------	------	------	------	------
	09	1220	224	0.0	6.0	794	------	0.0	0.0	0.0
	19	8110	384	52.6	72.7	283	154	205	535	143
	20	1820	766	0.0	38.0	525	34.3	455	502	492
	21	13,300	1460	------	312	------	------	------	------	------
	22	4990	732	------	112	------	------	------	------	------
B	08	50.4	5.1	0.0	7.1	0.30	------	31.6	------	------
	12	183	0.66	0.009	0.33	0.32	------	------	------	------
	17	920	7.97	0.0	2.17	------	409	52.2	------	70.6
	23	311	0.07	------	------	------	------	------	------	------
C	04	9050	1760	------	195	------	2280	------	------	------
	10	37,000	41.4	1.36	19.3	------	------	11,500	------	344
	11	28,500	2730	0.17	136	300	1590	------	------	------
	15	4660	244	0.0	0.20	------	1080	142	------	------
	19	2860	168	8.25	193	103	------	2610	696	220
	22	2390	------	------	125	------	------	------	------	------
D	03	483	5.47	0.30	1.37	42.0	31.3	31.3	177	------
	05	76.4	1.62	0.009	1.62	------	4.31	------	------	13.0
	17	513	6.45	0.01	8.43	------	149	13.1	------	14.1
	18		0.41	1.02	0.22	0.87	------	------	------	------
	24	241	7.2	------	1.9	------	------	------	------	------
E	05	30.9	2.68	0.002	0.90	------	3.40	------	------	5.0
	14	103	4.98	0.04	0.95	3.08	------	16.2	------	------
	17	243	6.75	0.02	8.6	------	35.2	47.6	------	38.2

TABLE V-4b - RAW WASTE LOADS

(kg/day)

Subcategory and Plant		Mg	Cn	PHENOL	Fe	Na	Pb	Hg	Cu	K
A	01	16.0	-----	-----	-----	165	-----	-----	-----	-----
	04	-----	-----	-----	-----	-----	-----	-----	-----	-----
	09	0.0	0.0	0.08	-----	465	0.0	0.0	0.0	32.2
	19	210	0.029	0.51	-----	242	-----	-----	-----	102
	20	2.9	-----	-----	0.0	-----	-----	-----	-----	-----
	21	-----	-----	-----	-----	-----	-----	-----	-----	-----
	22	-----	-----	-----	-----	-----	-----	-----	-----	-----
B	08	-----	0.006	0.006	-----	-----	-----	-----	-----	-----
	12	-----	0.04	-----	-----	50	-----	-----	-----	-----
	17	-----	-----	-----	0.50	-----	0.13	0.0	0.10	-----
	23	-----	-----	-----	-----	-----	-----	-----	-----	-----
C	04	-----	-----	-----	-----	-----	-----	-----	-----	-----
	10	-----	-----	-----	16.7	9500	-----	-----	-----	-----
	11	-----	-----	3.17	-----	-----	-----	-----	-----	-----
	15	-----	-----	-----	-----	-----	-----	-----	-----	-----
	19	64.2	0.02	1.84	-----	281	-----	-----	-----	151
	22	-----	-----	-----	-----	-----	-----	-----	-----	-----
D	03	-----	0.03	-----	0.79		0.15	0.001	0.24	-----
	05	-----	-----	-----	0.10	5.57	-----	-----	-----	-----
	17	-----	-----	-----	0.15	-----	0.02	0.0	0.02	-----
	18	-----	-----	-----	-----	-----	-----	-----	-----	-----
	24	-----	-----	-----	-----	-----	-----	-----	-----	-----
E	05	-----	-----	-----	0.02	2.48	-----	-----	-----	-----
	14	-----	-----	0.053	-----	-----	-----	-----	-----	-----
	17	-----	-----	-----	0.38	-----	0.04	0.002	0.19	-----

TABLE V-4c - RAW WASTE LOADS

(kg/day)

Subcategory and Plant		Cr	Zn	Al	As	Sulfide	Mn	Se
A	01	----	----	----	----	----	----	----
	04	----	----	----	----	----	----	----
	09	0.0	0.0	0.0	0.30	----	0.009	0.13
	19	0.18	----	----	----	----	----	----
	20	----	----	----	----	----	----	----
	21	----	----	----	----	----	----	----
	22	----	----	----	----	----	----	----
B	08	----	----	----	----	----	----	----
	12	----	----	0.04	----	----	----	----
	17	----	0.27	----	----	----	----	----
	23	----	----	----	----	----	----	----
C	04	----	----	----	----	----	----	----
	10	----	----	----	----	----	----	----
	11	----	----	----	----	----	----	----
	15	----	----	----	----	----	----	----
	19	0.20	----	----	14.4	----	----	----
	22	----	----	----	----	----	----	----
D	03	----	1.03	----	----	0.21	----	----
	05	----	----	----	----	----	----	----
	17	----	0.07	----	----	----	----	----
	18	----	----	----	----	----	----	----
	24	----	----	----	----	----	----	----
E	05	----	----	----	----	----	----	----
	14	----	----	----	----	----	----	----
	17	----	0.52	----	----	----	----	----

SECTION VI

SELECTION OF POLLUTANT PARAMETERS

General

From review of NPDES permit applications for direct discharge of wastewaters from various point sources grouped under pharmaceutical manufacturing and examination of related published data, twelve parameters (listed in Table VI-1) were selected and examined for all industrial wastewaters during the field data collection program. In addition, several specific parameters were examined for each individual pharmaceutical subcategory. All field sampling data are summarized in Supplement B. Supplement B includes laboratory analytical results, data from plants visited, RWL calculations, historical data, analysis of historical data, computer print-outs (showing flows, production and pollutants, performance data on treatment technologies and effluent limitations calculations). Supplements A (cost calculations) and B are available at the EPA Freedom of Information Center, Room 232, Waterside Mall, Washington, D.C. 20460.

The degree of impact on the overall environment has been used as a basis for dividing the pollutants into groups as follows:

1. Pollutants of significance.
2. Pollutants of specific significance.

The rationale and justification for pollutant categorization within the foregoing groupings, as discussed herein, will indicate the basis for selection of the parameters upon which the actual effluent limitations guidelines were postulated for each industrial category. In addition, particular parameters have been discussed in terms of their validity as measures of environmental impact and as sources of analytical insight.

Pollutants observed from the field data that were present in sufficient concentrations so as to interfere with, be incompatible with, or pass with inadequate treatment through publicly owned treatment works are discussed in Section XII of this document.

Pollutants of Significance

Parameters of pollution significance for the pharmaceutical manufacturing point source category are BOD5, COD, TOC and TSS.

BOD5, COD and TOC have been selected as pollutants of significance because they are the primary measurements of organic pollution. In the survey of the industrial categories, almost all of the effluent data collected from wastewater treatment facilities were based upon BOD5, because almost all the treatment facilities were biological processes. If other processes (such as evaporation, incineration, or activated carbon) are utilized, either COD or TOC may be a more appropriate measure of pollution. In either case, the COD parameter is highly reliable and rapidly measured.

Because historical data are usually not available for TOC, limitations will only be set for BOD5, COD and TSS at this time.

Table VI-1

List of Parameters to be Examined

Biochemical Oxygen Demand

Chemical Oxygen Demand

Total Organic Carbon

Total Dissolved Solids

Total Suspended Solids

Total Kjeldahl Nitrogen

Ammonia Nitrogen

Nitrate Nitrogen

pH

Alkalinity

Acidity

Total Phosphorus

RATIONALE FOR THE SELECTION OF POLLUTANT PARAMETERS

I. Pollutant Properties

Acidity and Alkalinity - pH

Although not a specific pollutant, pH is related to the acidity or alkalinity of a waste water stream. It is not a linear or direct measure of either, however, it may properly be used as a surrogate to control both excess acidity and excess alkalinity in water. The term pH is used to describe the hydrogen ion - hydroxyl ion balance in water. Technically, pH is the hydrogen ion concentration or activity present in a given solution. pH numbers are the negative logarithm of the hydrogen ion concentration. A pH of 7 generally indicates neutrality or a balance between free hydrogen and free hydroxyl ions. Solutions with a pH above 7 indicate that the solution is alkaline, while a pH below 7 indicates that the solution is acid.

Knowledge of the pH of water or wastewater is useful in determining necessary measures for corrosion control, pollution control and disinfection. Waters with a pH below 6.0 are corrosive to water works structures, distribution lines and household plumbing fixtures and such corrosion can add constituents to drinking water such as iron, copper, zinc, cadmium, and lead. Low pH waters not only tend to dissolve metals from structures and fixtures but also tend to redissolve or leach metals from sludges and bottom sediments. The hydrogen ion concentration can affect the "taste" of the water and at a low pH, water tastes "sour".

Extremes of pH or rapid pH changes can exert stress conditions or kill aquatic life outright. Even moderate changes from "acceptable" criteria limits of pH are deleterious to some species. The relative toxicity* to aquatic life of many materials is increased by changes in the water pH. For example, metalocyanide complexes can increase a thousand-fold in toxicity with a drop of 1.5 pH units. Similarly, the toxicity of ammonia is a function of pH. The bactericidal effect of chlorine in most cases is less as the pH increases and it is economically advantageous to keep the pH close to 7.

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*The term toxic or toxicity is used herein in the normal scientific sense of the word and not as a specialized term referring to section 307(a) of the Act.

Acidity is defined as the quantitative ability of a water to neutralize hydroxyl ions. It is usually expressed as the calcium carbonate equivalent of the hydroxyl ions neutralized. Acidity should not be confused with pH value. Acidity is the quantity of hydrogen ions which may be released to react with or neutralize hydroxyl ions while pH is a measure of the free hydrogen ions in a solution at the instant the pH measurement is made. A property of many chemicals, called buffering, may hold hydrogen ions in a solution from being in the free state and being measured as pH. The bond of most buffers is rather weak and hydrogen ions tend to be released from the buffer as needed to maintain a fixed pH value.

Highly acid waters are corrosive to metals, concrete and living organisms, exhibiting the pollutional characteristics outlined above for low pH waters. Depending on buffering capacity, water may have a higher total acidity at pH values of 6.0 than other waters with a pH value of 4.0.

Alkalinity: Alkalinity is defined as the ability of a water to neutralize hydrogen ions. It is usually expressed as the calcium carbonate equivalent of the hydrogen ions neutralized.

Alkalinity is commonly caused by the presence of carbonates, bicarbonates, hydroxides and to a lesser extent by borates, silicates, phosphates and organic substances. Because of the nature of the chemicals causing alkalinity and the buffering capacity of carbon dioxide in water, very high pH values are seldom found in natural waters.

Excess alkalinity as exhibited in a high pH value may make water corrosive to certain metals, detrimental to most natural organic materials and toxic to living organisms.

Ammonia is more lethal with a higher pH. The lacrimal fluid of the human eye has a pH of approximately 7.0 and a deviation of 0.1 pH unit from the norm may result in eye irritation for the swimmer. Appreciable irritation will cause severe pain.

Oil and Grease

Because of widespread use, oil and grease occur often in wastewater streams. These oily wastes may be classified as follows:

1. Light Hydrocarbons - These include light fuels such as gasoline, kerosene and jet fuel and

miscellaneous solvents used for industrial processing, degreasing, or cleaning purposes. The presence of these light hydrocarbons may make the removal of other heavier oily wastes more difficult.

2. Heavy Hydrocarbons, Fuels and Tars - These include the crude oils, diesel oils, #6 fuel oil, residual oils, slop oils and in some cases, asphalt and road tar.

3. Lubricants and Cutting Fluids - These generally fall into two classes: non-emulsifiable oils such as lubricating oils and greases and emulsifiable oils such as water soluble oils, rolling oils, cutting oils and drawing compounds. Emulsifiable oils may contain fat soap or various other additives.

4. Vegetable and Animal Fats and Oils - These originate primarily from processing of foods and natural products.

These compounds can settle or float and may exist as solids or liquids depending upon factors such as method of use, production process and temperature of waste water.

Oils and grease even in small quantities cause troublesome taste and odor problems. Scum lines from these agents are produced on water treatment basin walls and other containers. Fish and water fowl are adversely affected by oils in their habitat. Oil emulsions may adhere to the gills of fish causing suffocation and the flesh of fish is tainted when microorganisms that were exposed to waste oil are eaten. Deposition of oil in the bottom sediments of water can serve to inhibit normal benthic growth. Oil and grease exhibit an oxygen demand.

Levels of oil and grease which are toxic to aquatic organisms vary greatly, depending on the type and the species susceptibility. However, it has been reported that crude oil in concentrations as low as 0.3 mg/l is extremely toxic to fresh-water fish. It has been recommended that public water supply sources be essentially free from oil and grease.

Oil and grease in quantities of 100 l/sq km (10 gallons/sq mile) show up as a sheen on the surface of a body of water. The presence of oil slicks prevent the full aesthetic enjoyment of water. The presence of oil in water can also increase the toxicity of other substances being discharged into the receiving bodies of water. Municipalities frequently limit the quantity of oil and grease that can be discharged to their waste water treatment systems by industry.

Oxygen Demand (BOD, COD, TOC and DO)

Organic and some inorganic compounds can cause an oxygen demand to be exerted in a receiving body of water. Indigenous microorganisms utilize the organic wastes as an energy source and oxidize the organic matter. In doing so their natural respiratory activity will utilize the dissolved oxygen.

Dissolved oxygen (DO) in water is a quality that, in appropriate concentrations, is essential not only to keep organisms living but also to sustain species reproduction, vigor and the development of populations. Organisms undergo stress at reduced DO concentrations that make them less competitive and less able to sustain their species within the aquatic environment. For example, reduced DO concentrations have been shown to interfere with fish population through delayed hatching of eggs, reduced size and vigor of embryos, production of deformities in young, interference with food digestion, acceleration of blood clotting, decreased tolerance to certain toxicants, reduced food utilization efficiency, growth rate and maximum sustained swimming speed. Other organisms are likewise affected adversely during conditions of decreased DO. Since all aerobic aquatic organisms need a certain amount of oxygen, the consequences of total depletion of dissolved oxygen due to a high oxygen demand can kill all the inhabitants of the affected aquatic area.

It has been shown that fish may, under some natural conditions, become acclimatized to low oxygen concentrations. Within certain limits, fish can adjust their rate of respiration to compensate for changes in the concentration of dissolved oxygen. It is generally agreed, moreover, that those species which are sluggish in movement (e.g.,carp, pike, eel) can withstand lower oxygen concentrations than fish which are more lively in habit (such as trout or salmon).

The lethal affect of low concentrations of dissolved oxygen in water appears to be increased by the presence of toxic substances, such as ammonia, cyanides, zinc, lead, copper, or cresols. With so many factors influencing the effect of oxygen deficiency, it is difficult to estimate the minimum safe concentrations at which fish will be unharmed under natural conditions. Many investigations seem to indicate that a DO level of 5.0 mg/l is desirable for a good aquatic environment and higher DO levels are required for selected types of aquatic environments.

<u>Biochemical</u> <u>oxygen</u> <u>demand</u> <u>(BOD)</u> is the quantity of oxygen required for the biological and chemical oxidation of waterborne substances under ambient or test conditions. Materials which may contribute to the BOD include: carbonaceous organic materials usable as a food source by aerobic organisms; oxidizable nitrogen derived from nitrites, ammonia and organic nitrogen compounds which serve as food for specific bacteria; and certain chemically oxidizable materials such as ferrous iron, sulfides, sulfite, etc. which will react with dissolved oxygen or are metabolized by bacteria. In most industrial and municipal wastewaters, the BOD derives principally from organic materials and from ammonia (which is itself derived from animal or vegetable matter).

The BOD of a waste exerts an adverse effect upon the dissolved oxygen resources of a body of water by reducing the oxygen available to fish, plant life and other aquatic species. Conditions can be reached where all of the dissolved oxygen in the water is utilized resulting in anaerobic conditions and the production of undesirable gases such as hydrogen sulfide and methane. The reduction of dissolved oxygen can be detrimental to fish populations, fish growth rate, and organisms used as fish food. A total lack of oxygen due to the exertion of an excessive BOD can result in the death of all aerobic aquatic inhabitants in the affected area.

Water with a high BOD indicates the presence of decomposing organic matter and associated increased bacterial concentrations that degrade its quality and potential uses. A by-product of high BOD concentrations can be increased algal concentrations and blooms which result from decomposition of the organic matter and which form the basis of algal populations.

The $BOD\underline{5}$ (5-day BOD) test is used widely to estimate the pollutional strength of domestic and industrial wastes in terms of the oxygen that they will require if discharged into receiving streams. The test is an important one in water pollution control activities. It is used for pollution control regulatory activities, to evaluate the design and efficiencies of waste water treatment works and to indicate the state of purification or pollution of receiving bodies of water.

Complete biochemical oxidation of a given waste may require a period of incubation too long for practical analytical test purposes. For this reason, the 5-day period has been accepted as standard and the test results have been designated as BOD5. Specific chemical test methods are not readily available for measuring the quantity of many degradable substances and their reaction products. Reliance in such cases is placed on the collective parameter, BOD5, which measures the weight of dissolved oxygen utilized by microorganisms as they oxidize or transform the gross mixture of chemical compounds in the waste water. The biochemical reactions involved in the oxidation of carbon compounds are related to the period of incubation. The five-day BOD normally measures only 30 to 40% of the total organic oxygen demand of the sample, and for many purposes this is a reasonable parameter. Additionally, it can be used to estimate the gross quantity of oxidizable organic matter.

The BOD5 test is essentially a bioassay procedure which provides an estimate of the oxygen consumed by microorganisms utilizing the degradable matter present in a waste under conditions that are representative of those that are likely to occur in nature. Standard conditions of time, temperature, suggested microbial seed and dilution water for the wastes have been defined and are incorporated in the standard analytical procedure. Through the use of this procedure, the oxygen demand of diverse wastes can be compared and evaluated for pollution potential and to some extent for treatability by biological treatment processes.

Because the BOD test is a bioassay procedure, it is important that the environmental conditions of the test be suitable for the microorganisms to function in an uninhibited manner at all times. This means that toxic substances must be absent and that the necessary nutrients, such as nitrogen, phosphorous and trace elements, must be present.

Chemical oxygen demand (COD) is a purely chemical oxidation test devised as an alternate method of estimating the total oxygen demand of a waste water. Since the method relies on the oxidation-reduction system of chemical analyses rather than on biological factors, it is more precise, accurate, and rapid than the BOD test. The COD test is widely used to estimate the total oxygen demand (ultimate rather than 5-day BOD) to oxidize the compounds in a waste water. It is based on the fact that organic compounds, with a few exceptions, can be oxidized by strong chemical oxidizing agents under acid conditions with the assistance of certain inorganic catalysts.

The COD test measures the oxygen demand of compounds that are biologically degradable and of many that are not. Pollutants which are measured by the BOD_5 test will be measured by the COD test. In addition, pollutants which are more resistant to biological oxidation will also be measured as COD. COD is a more inclusive measure of oxygen demand than is BOD_5 and will result in higher oxygen demand values than will the BOD_5 test.

The compounds which are more resistant to biological oxidation are becoming of greater and greater concern not only because of their slow but continuing oxygen demand on the resources of the receiving water, but also because of their potential health effects on aquatic life and humans. Many of these compounds result from industrial discharges and some have been found to have carcinogenic, mutagenic and similar adverse effects, either singly or in combination. Concern about these compounds has increased as a result of demonstrations that their long life in receiving waters - the result of a slow biochemical oxidation rate - allows them to contaminate downstream water intakes. The commonly used systems of water purification are not effective in removing these types of materials and disinfection such as chlorination may convert them into even more hazardous materials.

Thus the COD test measures organic matter which exerts an oxygen demand and which may affect the health of the people. It is a useful analytical tool for pollution control activities. It provides a more rapid measurement of the oxygen demand and an estimate of organic compounds which are not measured in the BOD_5 test.

Total organic carbon (TOC) is measured by the catalytic conversion of organic carbon in a waste water to carbon dioxide. Most organic chemicals have been found to be measured quantitatively by the equipment now in use. The time of analyses is short, from 5 to 10 minutes, permitting a rapid and accurate estimate of the organic carbon content of the waste waters to be made by relatively unskilled personnel.

A TOC value does not indicate the rate at which the carbon compounds are oxidized in the natural environment. The TOC test will measure compounds that are readily biodegradable and measured by the BOD5 test as well as those that are not. TOC analyses will include those biologically resistant organic compounds that are of concern in the environment.

BOD and COD methods of analyses are based on oxygen utilization of the waste water. The TOC analyses estimates the total carbon content of a waste water. There is as yet no fundamental correlation of TOC to either BOD or COD. However, where organic laden waste waters are fairly uniform, there will be a fairly constant correlation among TOC, BOD and COD. Once such a correlation is established, TOC can be used as an inexpensive test for routine process monitoring.

Total Suspended Solids (TSS)

Suspended solids include both organic and inorganic materials. The inorganic compounds include sand, silt and clay. The organic fraction includes such materials as grease, oil, tar and animal and vegetable waste products. These solids may settle out rapidly and bottom deposits are often a mixture of both organic and inorganic solids. Solids may be suspended in water for a time and then settle to the bed of the stream or lake. These solids discharged with man's wastes may be inert, slowly biodegradable materials, or rapidly decomposable substances. While in suspension, they increase the turbidity of the water, reduce light penetration and impair the photosynthetic activity of aquatic plants.

Suspended solids in water interfere with many industrial processes, cause foaming in boilers and incrustations on equipment exposed to such water, especially as the temperature rises. They are undesirable in process water used in the manufacture of steel, in the textile industry, in laundries, in dyeing and in cooling systems.

Solids in suspension are aesthetically displeasing. When they settle to form sludge deposits on the stream or lake bed, they are often damaging to the life in water. Solids, when transformed to sludge deposits, may do a variety of damaging things, including blanketing the stream or lake bed and thereby destroying the living spaces for those benthic organisms that would otherwise occupy the habitat. When of an organic nature, solids use a portion or all of the dissolved oxygen available in the area.

Disregarding any toxic effect attributable to substances leached out by water, suspended solids may kill fish and shellfish by causing abrasive injuries and by clogging the gills and respiratory passages of various aquatic fauna. Indirectly, suspended solids are inimical to aquatic life because they screen out light and they promote and maintain the development of noxious conditions through oxygen depletion. This results in the killing of fish and fish food organisms. Suspended solids also reduce the recreational value of the water.

Turbidity: Turbidity of water is related to the amount of suspended and colloidal matter contained in the water. It affects the clearness and penetration of light. The degree of turbidity is only an expression of one effect of suspended solids upon the character of the water. Turbidity can reduce the effectiveness of chlorination and can result in difficulties in meeting BOD and suspended solids limitations. Turbidity is an indirect measure of suspended solids.

II. Pollutant Materials

Ammonia (NH_3)

Ammonia occurs in surface and ground waters as a result of the decomposition of nitrogenous organic matter. It is one of the constituents of the complex nitrogen cycle. It may also result from the discharge of industrial wastes from chemical or gas plants, from refrigeration plants, and from the manufacture of certain organic and inorganic chemicals. Because ammonia may be indicative of pollution and because it increases the chlorine demand, it is recommended that ammonia nitrogen in public water supply sources not exceed 0.5 mg/l.

Ammonia exists in its non-ionized form only at higher pH levels and is most toxic in this state. The lower the pH, the more ionized ammonia is formed and its toxicity decreases. Ammonia, in the presence of dissolved oxygen, is converted to nitrate (NO_3) by nitrifying bacteria. Nitrite (NO_2), which is an intermediate product between ammonia and nitrate, sometimes occurs in quantity when depressed oxygen conditions permit. Ammonia can exist in several other chemical combinations including ammonium chloride and other salts.

Nitrates are considered to be among the objectionable components of mineralized waters. Excess nitrates cause irritation to the gastrointestinal tract, causing diarrhea and diuresis. Methemoglobinemia, a condition characterized by cyanosis and which can result in infant and animal deaths, can be caused by high nitrate concentrations in waters used for feeding. Ammonia can exist in several other chemical combinations, including ammonium chloride and other salts. Evidence exists that ammonia exerts a toxic effect on all aquatic life depending upon the pH, dissolved oxygen level and the total ammonia concentration in the water. A significant oxygen demand can result from the microbial oxidation of ammonia. Approximately 4.5 grams of oxygen are required for every gram of ammonia that is oxidized. Ammonia can add to eutrophication problems by supplying nitrogen to aquatic life. Ammonia can be toxic, exerts an oxygen demand and contributes to eutrophication.

Cyanide (CN)

Cyanide is a compound that is widely used in industry primarily as sodium cyanide (NaCN) or hydrocyanic acid (HCN). The major use of cyanides is in the electroplating industry where cyanide baths are used to hold ions such as zinc and cadmium in solution. Cyanides in various compounds are also used in steel plants, chemical plants, photographic processing, textile dyeing and ore processing.

Of all the cyanides, hydrogen cyanide (HCN) is probably the most acutely lethal compound. HCN dissociates in water to hydrogen ions and cyanide ions in a pH dependent reaction. The cyanide ion is less acutely lethal than HCN. The relationship of pH to HCN shows that as the pH is lowered to below 7 there is less than 1% of the cyanide molecules in the form of the CN ion and the rest is present as HCN. When the pH is increased to 8, 9 and 10, the percentage of cyanide present as CN ion is 6.7, 42 and 87%, respectively. The toxicity of cyanides is also increased by increases in temperature and reductions in oxygen tensions. A temperature rise of 10°C produced a two- to threefold increase in the rate of the lethal action of cyanide.

In the body, the CN ion, except for a small portion exhaled, is rapidly changed into a relatively non-toxic complex (thiocyanate) in the liver and eliminated in the urine. There is no evidence that the CN ion is stored in the body. The safe ingested limit of cyanide has been estimated at something less than 18 mg/day, part of which comes from normal environment and industrial exposure. The average fatal dose of HCN by ingestion by man is 50 to 60 mg. It has been recommended that a limit of 0.2 mg/l cyanide not be exceeded in public water supply sources.

The harmful effects of the cyanides on aquatic life are affected by the pH, temperature, dissolved oxygen content and the concentration of minerals in the water. The biochemical degradation of cyanide is not affected by temperature in the range of 10 degrees C to 35 degrees C while the toxicity of HCN is increased at higher temperatures.

On lower forms of life and organisms, cyanide does not seem to be as toxic as it is toward fish. The organisms that digest BOD were found to be inhibited at 1.0 mg/l and at 60 mg/l although the effect is more one of delay in exertion of BOD than total reduction.

Certain metals such as nickel may complex with cyanide to reduce lethality, especially at higher pH values. On the other hand, zinc and cadmium cyanide complexes may be exceedingly toxic.

Mercury (Hg)

Mercury is an elemental metal that is rarely found in nature as a free metal. The most distinguishing feature is that it is a liquid at ambient conditions. Mercury is relatively inert chemically and is insoluble in water. Its salts occur in nature chiefly as the sulfide (HgS) known as cinebar.

Mercury is used extensively in measuring instruments and in mercury batteries. It is also used in electroplating, in chemical manufacturing and in some pigments for paints. The electrical equipment industry uses mercury in the manufacture of lamp switches and other devices.

Mercury can be introduced into the body through the skin and the respiratory system. Mercuric salts are highly toxic to humans and can be readily absorbed through the gastrointestinal tract. Fatal doses can vary from 3 to 30 grams. The total mercury in public water supply sources has been recommended not to exceed 0.002 mg/l.

Mercuric salts are extremely toxic to fish and other aquatic life. Mercuric chloride is more lethal than copper, hexavalent chromium, zinc, nickel and lead towards fish and aquatic life. In the food cycle, algae containing mercury up to 100 times the concentration of the surrounding sea water are eaten by fish which further concentrate the mercury and predators that eat the fish in turn concentrate the mercury even further.

Phosphorus

Phosphorus occurs in natural waters and in wastewaters in the form of various types of phosphate. These forms are commonly classified into orthophosphates, condensed phosphates (pyro-, meta- and polyphosphorus) and organically bound phosphates. These may occur in the soluble form, in particles of detritus or in the bodies of aquatic organisms.

The various forms of phosphates find their way into waste waters from a variety of industrial, residential and commercial sources. Small amounts of certain condensed phosphates are added to some water supplies in the course of potable water treatment. Large quantities of the same compounds may be added when the water is used for laundering or other cleaning since these materials are major constituents of many commercial cleaning preparations. Phosphate coating of metals is another major source of phosphates in certain industrial effluents.

The increasing problem of the growth of algae in streams and lakes appears to be associated with the increasing presence of certain dissolved nutrients, chief among which is phosphorus. Phosphorus is an element which is essential to the growth of organisms and it can often be the nutrient that limits the aquatic growth that a body of water can support. In instances where phosphorus is a growth limiting nutrient, the discharge of sewage, agricultural drainage or certain industrial wastes to a receiving water may stimulate the growth, in nuisance quantities, of photosynthetic aquatic microorganisms and macroorganisms.

The increase in organic matter production by algae and plants in a lake undergoing eutrophication has ramifications throughout the aquatic ecosystem. Greater demand is placed on the dissolved oxygen in the water as the organic matter decomposes at the termination of the life cycles. Because of this process, the deeper waters of the lake may become entirely depleted of oxygen, thereby, destroying fish habitats and leading to the elimination of desirable species. The settling of particulate matter from the productive upper layers changes the character of the bottom mud, also leading to the replacement of certain species by less desirable organisms. Of great importance is the fact that nutrients inadvertently introduced to a lake are, for the most part, trapped there and recycled in accelerated biological processes. Consequently, the damage done to a lake in a relatively short time requires a many fold increase in time for recovery of the lake.

When a plant population is stimulated in production and attains a nuisance status, a large number of associated liabilities are immediately apparent. Dense populations of pond weeds make swimming dangerous. Boating and water skiing and sometimes fishing may be eliminated because of the mass of vegetation that serves as an physical impediment to such activities. Plant populations have been associated with stunted fish populations and with poor fishing. Plant nuisances emit vile stenches, impart tastes and odors to water supplies, reduce the efficiency of industrial and municipal water treatment, impair aesthetic beauty, reduce or restrict resort trade, lower waterfront property values, cause skin rashes to man during water contact and serve as a desired substrate and breeding grcund for flies.

Phosphorus in the elemental form is particularly toxic, and subject to bioaccumulation in much the same way as mercury. Colloidal elemental phosphorus will poison marine fish (causing skin tissue breakdown and discoloration). Also, phosphorus is capable of being concentrated and will accumulate in organs and soft tissues. Experiments have shown that marine fish will concentrate phosphorus from water containing as little as 1 ug/l.

Nitrogen

Ammonia nitrogen (NH_3-N) and total Kjeldahl nitrogen (TKN) are two parameters which have received a substantial amount of interest in the last decade. TKN is the sum of the NH_3-N and organic nitrogen present in the sample. Both NH_3 and TKN are expressed in terms of equivalent nitrogen values in mg/l to facilitate mathematical manipulations of the values.

Organic nitrogen may be converted in the environment to ammonia by saprophytic bacteria under either aerobic or anaerobic conditions. The ammonia nitrogen then becomes the nitrogen and energy source for autotrophic organisms (nitrifiers). The oxidation of ammonia to nitrite and then to nitrate has a stoichiometric oxygen requirement of approximately 4.5 times the concentration of NH_3-N. The nitrification reaction is much slower than the carbonaceous reactions and, therefore, the dissolved oxygen utilization is observed over a much longer pericd.

Pollutants of Specific Significance

In addition to the parameters already discussed, there are pollutants specific to various individual industry categories of the miscellaneous chemicals industry. These will be covered as applicable to the industry discussions as is done in the following text for the pharmaceutical manufacturing industry.

Pharmaceutical Manufacturing Industry

Review of raw waste load (RWL) data indicates that the pollutants of special significance to the pharmaceutical manufacturing point source category, in addition to BOD5, COD, TOC and TSS are: mercury, cyanide, ammonia nitrogen, organic nitrogen and total phosphorus. The raw waste loads computed for all parameters analyzed in the field are presented in Table V-4, except for BOD5, COD, TOC and TSS (which are presented in Tables V-1a and V-1b).

Toxicity

Toxicity is classified as either acute or chronic. Acute toxicity is characterized by the rapid onset of negative physiological effects upon exposure, whereas chronic toxicity is usally manifested by the appearance of negative physiological effects after a prolonged dosage of a chemical at concentrations below the acute level. The latter effect is often the result of the accumulation of the toxic compound in the tissues of the organism. One complicating factor in trying to understand toxicity is the synergistic or antagonistic effect of various chemicals. For example, mature fish have been killed by 0.1 mg/l of lead in water containing 1 mg/l of calcium, but have not been harmed by this concentration of lead in water containing 50 mg/l of calcium.

Mercury and Cyanide

Numerous synthetic mercuric salts are used by the pharmaceutical industry to produce medicinal products and disinfectants. Cyanide salts are used by the industry as catalysts in certain chemcial synthesis processes (amination). The presence of mercury and/or cyanide in wastewaters from these processes may have toxic effects on the biological unit operations of a wastewater treatment plant and thus cause it to be ineffective.

The U.S. Public Health Service (USPHS) drinking water standards specify a maximum allowable cyanide concentration of 0.01 mg/l, as CN-. "U.S. Environmental Protection Agency Preliminary Draft of Interim Primary Drinking Water Standards" proposes a limit of 0.002 mg/l of mercury.

Only minimal concentrations of mercury and cyanide were observed in most of the RWL data. This is attributed to the various in-plant pollutant abatement measures currently practiced in the pharmaceutical manufacturing industry (i.e., metals recovery, cyanide destruction). It is emphasized that the end-of-pipe treatment models proposed in this study should be used in conjunction with these in-plant practices. Their expanded use, wherever feasible and improvement of current in-plant contaminant reduction systems are also encouraged.

Nitrogen

Ammonia nitrogen and organic nitrogen have been previously discussed. High concentrations of organic and inorganic nitrogen were observed in the RWL data for the pharmaceutical industry. As federal, state and local effluent discharge standards become more stringent, it is inevitable that maximum allowable discharge limitations will be adopted for the various forms of nitrogen and that nitrogen removal will become a major requirement of the pharmaceutical manufacturing point source category. However, the selection of ammonia and organic nitrogen discharge standards shall be related to local conditions.

Phosphorus

Phosphorus compounds are used by some segments of the pharmaceutical industry. High total phosphorus concentrations were observed in the raw water from plants in subcategories A and C. Phosphorus is often a limiting nutrient in many water courses; consequently, elevated phosphorus concentrations often lead to algae blooms and steady degradation of impounded waters. The selection of standards for discharge of phosphorus shall be related to local conditions.

SECTION VII

CONTROL AND TREATMENT TECHNOLOGIES

General

The entire spectrum of wastewater control and treatment technology is available to the pharmaceutical manufacturing segment. The selection of technology options depends on the economics of that technology and the magnitude of the final effluent concentration. Control and treatment technology may be divided into two major groupings: in-plant pollution abatement and end-of-pipe treatment.

After discussing the available performance data for each of the subcategories covered under pharmaceutical manufacturing, conclusions will be made relative to the reduction of various pollutants commensurate with the following distinct technology levels:

I. Best Practicable Control Technology Currently Available (BPT)

II. Best Available Technology Economically Achievable (BAT)

III. Best Available Demonstrated Control Technology (NSPS)

To facilitate the economic analysis of these proposed effluent limitations and guidelines, model treatment systems have been proposed which are considered capable of attaining the recommended RWL reduction. It should be noted and understood that the particular systems have been chosen for use in the economic analysis only and are not the only systems capable of attaining the specified pollutant reductions.

It is the intent of this study to allow the individual plant to make the final decision about what specific combination of pollution control measures is best suited to its situation in complying with the limitations and standards presented in this report.

Pharmaceutical Manufacturing

General

Pharmaceutical wastewaters vary in quantity and quality depending on the type of manufacturing activities employed by the various segments of the industry. However, in general, the wastes are readily treatable. 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. With such information one could determine the pollutional effect of substitution of one alternative subprocess for another, or of improving operating and housekeeping practices in general. This kind of information was not readily available, as the survey contractor in most instances was not permitted to review manufacturing processes in sufficient detail to develop such information.

Despite this lack of specific process wastewater data, there is information of a more general nature which 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 are discussed below:

Housekeeping and General Practices

In general, operating and housekeeping practices within the pharmaceutical industry appear to be excellent. The competitive nature of the industry, combined with strict regulations from the Food and Drug Administration, requires most producers to operate their plants in the most efficient manner possible. 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 by 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.

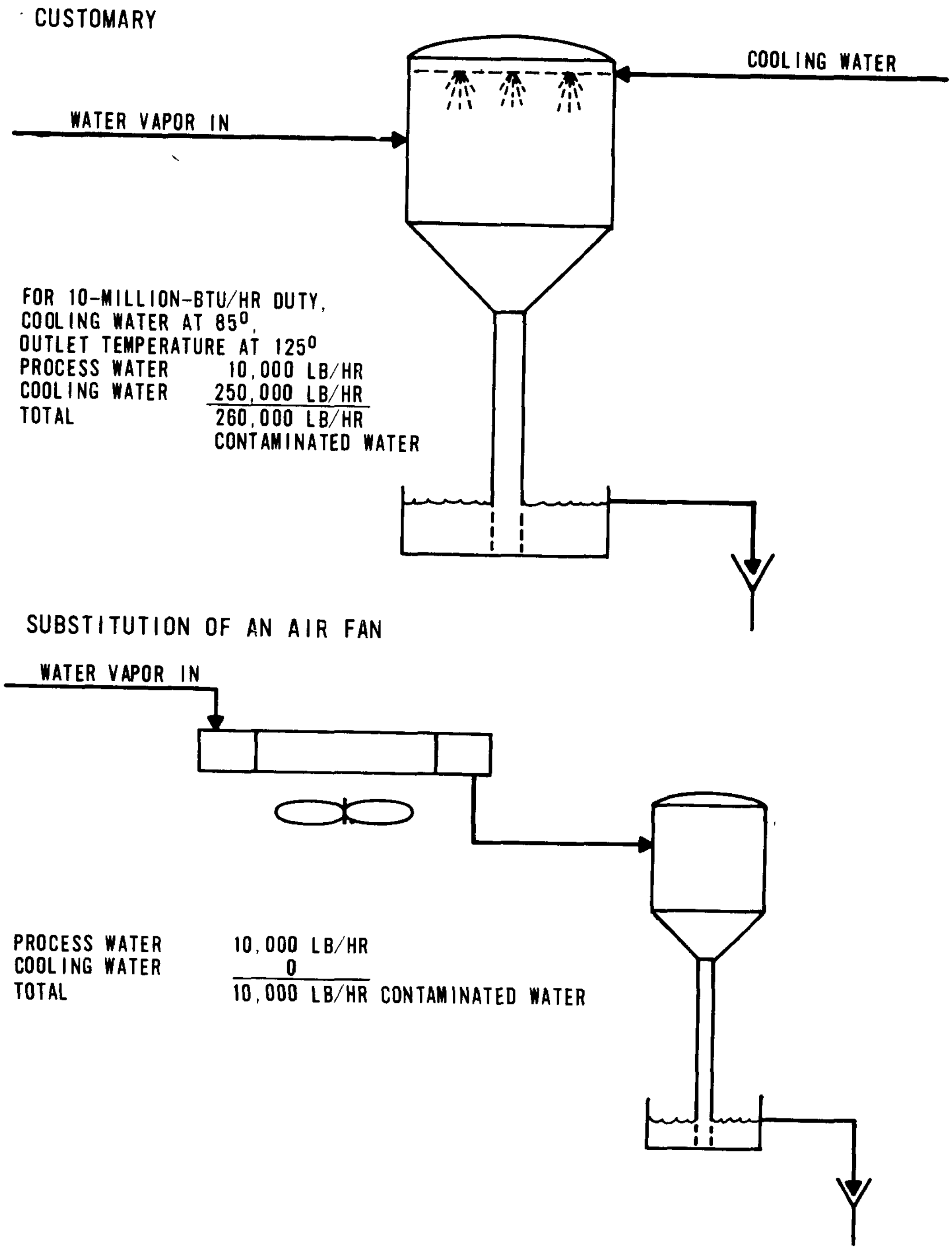
3. Quality control laboratories are an integral part of the pharmaceutical manufacturing industry. Solvent and toxic substance disposal practices within the laboratories are further evidence of the apparent industry-wide commitment to good housekeeping. Standard practice throughout the industry is to 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 efficiently 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 permit limits it is then automatically diverted to the waste

FIGURE VII -1

BAROMETRIC CONDENSER



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 widespread 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 in 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 and subsequent minimization of contamination 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 (Figure VII-1) 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 an exchanger for water sprays as shown on Figure VII-1. 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 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 (19) 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. Several plants have installed automatic TOC 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 (08, 12, 17) in subcategory B (Biological Products) segregate the spent eggs used on virus production and the waste plasma or blood fractions used in blood fractionation procedures. They are disposed of by incineration at these plants.

8. Substitution of chemicals in this industry may be possible, but only when this practice would not constitute a process change that could result in an intrinsic change in the production requiring approval by the FDA.

9. Some plants practice ocean discharges or deep-well injection following a pretreatment to dispose of process wastewater. Recent regulations tend to limit the use of ocean discharge and deep-well injection because of the potential long-term detrimental effects associated with these disposal procedures. Hence, these practices are not encouraged.

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 manufacturing point source category are varied and only a few examples are described briefly below:

1. Reduction of once-through cooling water by recycling through cooling towers is used in numerous plants and results in decreased total volume of discharge.

2. Once-through non-contact surface condenser waters are reused as waste combustion scrubber waters by one pharmaceutical plant (01). 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 to product contamination.

3. Several plants (e.g.,17) reuse waste deionized rinse water for cooling tower makeup.

4. Waste cooling water from one plant (18) was collected in an aesthetically located pond and held as a source of water for fire protection.

At-Source Pretreatment

The survey indicated that at-source pretreatment to protect downstream biological treatment plants was practiced by very few plants on an industry-wide basis. Those manufacturing plants utilizing at-source pretreatment were mostly in subcategory 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 treatment involving biological activity (oxidation lagoons and deep trickling filters). 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 N_2 and CO_2. 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 (11).

Cyanide removal can also be accomplished by electrolytic destruction (26) and by ozonization (27).

Mercury Removal

Mercury removal can be accomplished by other techniques (18) such as sulfide precipitation, ion exchange, reduction, or adsorption. One manufacturing plant (02) 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 (05, 11) 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.

Sewer Segregation

Wastewater quantity is one of the major factors that affects the cost of waste treatment facilities. In order to provide efficient treatment of the wastes originating within a pharmaceutical plant it is important to consider segregation of concentrated waste streams, since it frequently simplifies waste treatment problems. Segregation and pretreatment of a process waste stream may be desirable where some specific pollutant can be removed more efficiently while it is present in its most concentrated form. Examples are the removal of ammonia or organic solvents by steam stripping and the use of various processes to remove metal-bearing waste. Some highly concentrated wastes should be disposed of by a licensed scavenger rather than by addition to the wastewater stream.

Segregation and incineration of strong waste streams is being practiced by many pharmaceutical plants; however, potential for further segregation still exists. It is conceivable that plants utilizing a variety of manufacturing processes could further separate their waste streams to optimize the overall treatment efficiency of their waste treatment program. For example, some plants might find that the most cost-effective waste treatment program would include incineration of extremely concentrated waste, biological treatment of intermediate strength waste and dilution of weak strength wastes with the effluent from the biological treatment plant. The feasibility of such an approach should be examined by plants when they consider treatment systems for achievement of BAT effluent limitations.

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 is also a demonstrated practice in the pharmaceutical industry which permits effective removal of such pollutants as metals, arsenic, ammonia, cyanide and other chemicals that may be toxic or inhibitory to biological treatment systems.

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 facilitates water reuse either prior to or after treatment.

Conditions Which Inhibit Flocculation

Floc formation in the activated sludge process is adversely affected by sulfides, other sulfur compounds, nutrient imbalance, oxygen deficiency, low temperatures and organic acids (notably acetic acid). Although not pollution parameters identified in this document, these conditions may result in filamentous or pinpoint flocs which could cause poor separation of activated sludge in secondary clarifiers of plants in subcategories A and C.

General Toxicity

It is not possible to ascertain the toxicity of a wastewater by chemical analyses, although toxicity may occasionally be discovered by the finding of a particular toxicant. A bioassay using fish, while not ideal, is the best indicator of total toxicity. For the pharmaceutical industry, the

Table VII-1

Treatment Technology Survey

Pharmaceutical Industry

TYPE OF TREATMENT OR DISPOSAL FACILITY	NUMBER OF TREATMENT FACILITIES OBSERVED DURING FIELD SURVEY	PLANT NO.
Activated Sludge	12	02,05,11,19 15,20,02,14 23,24,25,26*
Activated Sludge/Polishing Pond	2	10,16
Activated Sludge/Phosphate Precipitation	1	14
Bio-Filter/Activated Sludge	4	04,18,21,22
Aerated Lagoons	-	
Aerated Lagoon/Settling Pond-Polishing Cascade	1	09
Aerated Lagoon/Phosphate Precipitation	1	08
Trickling Filters	-	
Evaporation	1	01
Thermal Oxidation	1	01
Pretreatment/To Municipal Treatment Plant (H_2O_2+ Oxinite Addition)	1	17
To Municipal Treatment	2	03,12

* Activated Sludge using Oxygen

bioassay should be an important tool in the detection and control of toxicity.

Since a bioassay is a relatively expensive test, it is not feasible to make it a required test at frequent intervals. If a test is made at semi-annual or quarterly intervals, or even monthly, it will not be effective in detecting occasional discharges of poisons. A continuous bioassay is a feasible technique, requiring only that the effluent or a portion of the effluent be run through a suitable pond in which the fish are kept.

End-of-pipe Control Technology

Table VII-1 indicates the types of wastewater treatment technology observed during the survey and the treatment systems identified by consultation with EPA regional offices. End-of-pipe control technology in the pharmaceutical manufacturing point source category relies heavily upon the use of biological treatment methods. Primary treatment most often consists of equalization basins to minimize shock organic loads, neutralization to ensure optimum conditions and clarifiers to remove solids. Other primary treatment 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 (01) 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 treating pharmaceutical wastewaters although the literature indicates that some applications are in existence.

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. The evaporation and the thermal oxidation of strong waste water 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. Deep-well injection and ocean disposal are being practiced for strong chemical wastes, but recent regulations limit the use of ocean discharge and deep-well injection because of the potential long-term detrimental effects associated with these disposal procedures. As a result of Public Law 93-523, EPA is in the process of developing guidelines which cover deep-well injection of potentially hazardous wastewaters. Other techniques, including reverse osmosis,

TABLE VII - 2a

Summary of Statistical Analysis of
Historical Data

Effluent BOD mg/1

Plant No.	Sub-cat	P_{10}	P_{50}	P_{90}	P_{95}	P_{98}	Avg.	P_{90}/Avg	P_{95}/Avg	P_{98}/Ave	Data Base
08	B	1.8	3.6	13	25	88	7.7	1.7	3.2	11.4	Bi-Weekly 1/74-10-74[a]
11	C	29	51	163	194	276	79	2.1	2.4	3.5	Bi-Weekly 1/73-8/74
14	E	0.9	1.4	2.9	4.6	7.3	1.8	1.6	2.6	4.1	Daily 1/74-9/74
19	ACD	23	57	157	205	290	82	1.9	2.5	3.5	Daily 5/75-12/75[b]
22*	AC	16	28	48	59	79	31	1.5	1.9	2.5	Daily 1/74-12/75
23	BDE	0.7	1.2	2.2	2.5	3.0	1.3	1.7	1.9	2.3	Weekly 1/74-12/75
24	DE	4	10	22	25	32	12	1.8	2.1	2.7	Weekly 4/74-3/76

* Includes cooling water

a 10 month period used for statistical analysis only

b 8 month period used for statistical analysis only

TABLE VII - 2b

Summary of Statistical Analysis
of Historical Data

Effluent COD mg/l

Plant No.	Sub-cat	P_{10}	P_{50}	P_{90}	P_{95}	P_{98}	Avg	P_{90}/Avg	P_{95}/Avg	P_{98}/Avg	Data Base
08	B	21	33	68	126	178	43	1.6	2.9	4.1	Daily 1/74-10-74[a]
11	C	234	382	584	690	785	398	1.5	1.7	2.0	Daily 1/73-8/74
14	E	11	17	26	32	41	18	1.4	1.8	2.3	Daily 1/74-9/74
15	C	6400	13,400	21,200	25,100	30,100	14,000	1.5	1.8	2.2	Daily 1/73-9/74
22*	AC	158	240	320	352	382	218	1.5	1.6	1.8	Daily 1/74-12/75
23	BDE	29	59	95	98	126	62	1.5	1.6	2.0	Weekly 1/74-12/75
24	DE	30	53	102	107	115	58	1.8	1.8	2.0	Daily 4/75-3/76

* Includes cooling water

[a] 10 month period used for statistical analysis only

TABLE VII - 2c

Summary of Statistical Analysis of Historical Data

Effluent TSS mg/1

Plant No.	Sub-cat	P_{10}	P_{50}	P_{90}	P_{95}	P_{98}	Avg	P_{90}/Avg	P_{95}/Avg	P_{98}/Avg	Data Base
08	B	11	21	40	46	49	23	1.7	2.0	2.1	Daily 1/74-10-74[a]
11	C	24	53	143	188	290	71	2.0	2.6	4.1	Daily 1/73-8/74
14	E	1.0	3.9	13	18	27	5.9	2.2	3.0	4.6	Daily 1/74-9/74
15	C	52	205	755	1460	2140	359	2.1	4.1	6.0	Daily 1/73-9/74
19	ACD	42	92	307	500	870	154	2.0	3.2	5.6	Daily 5/75-12/75[b]
22*	AC	16	33	64	76	96	35	1.8	2.2	2.7	Daily 1/75-12/75
23	BDE	9	17	36	40	50	20	1.8	2.0	2.5	Semi-Weekly 1/74-12/75
24	DE	13	26	58	60	74	28	2.1	2.1	2.6	Weekly 4/74-3/76

* Includes cooling water

a 10 month period used for statistical analysis only

b 8 month period used for statistical analysis only.

ultrafiltration, ozonization and ion exchange, are being studied and have good potential. For treating strong pharmaceutical wastewater, an activated sludge using pure oxygen system is utilized by a pharmaceutical plant.

One of the initial criteria used to screen pharmaceutical plants for the field survey was the degree of treatment provided by the wastewater treatment facilities. During the survey program historical wastewater treatment plant performance was obtained when possible. The historical data were analyzed statistically and the individual plant's performance evaluated. Summary historical data for effluent BOD_5 in mg/l is shown in Table VII-2a. Effluent COD and TSS data are presented in Tables VII-2b and VII-2c respectively.

Differences in performance among different plants of subcategories A and C do not appear to be explainable entirely on the basis of some treatment plants being better designed or better operated than others. Among plants that have very competent operators and that are designed according to good engineering standards for the types of processes used, there are substantial differences of performance. In the same plant there are differences from day to day and from month to month. In determining BPT, plants are not arbitrarily included or excluded purely on the basis of performance. A plant has been excluded if poor performance appears to be traceable to poor design or operation. Plants have been also excluded that are distinctly non-typical in respect to the kind of wastewaters treated, or in the use of wastewater processes that are not well enough established to allow a conclusion that they are generally applicable. Specifically, thermal oxidation of strong wastewaters is a process that could have high fuel costs, which may have economic impacts greater than justifiable by current fuel economics and that could have operating problems due to the salt content of the wastewaters. It may prove to be the best method of treatment, but this cannot be considered to be an established fact at this time. An extremely complicated process, or one that requires the use of land in amounts not generally available cannot be used as examples of generally practicable technologies. A large user of land (Plant 21) is included, however, as an example of performance of that part of the treatment processes that preceeds the large final oxidation pond.

Wastewaters from the various subcategories of the pharmaceutical manufacturing point source category do not have the same relative organic concentrations in the influent to the wastewater treatment plant. Subcategories B and E and generally also D, produce wastewaters with

12/6/76

TABLE VII - 3a

Treatment Plant Performance Data

Plant	Subcat.	Flow cu m/day	N[a]	BOD (mg/1) Infl.	BOD (mg/1) Effl.	BOD (mg/1) % Rmvl.	COD (mg/1) Infl.	COD (mg/1) Effl.	COD (mg/1) % Rmvl.	TSS Effl. mg/1
01 S	AC					99				
02 H	A	2297	360	4250	308	93	7760	1530	80	666
02 H	C	923	360	5830	525	91	15,600	3280	79	362
03 S	BD	1530	2	178	b		416	b		
04 H	AC	3840	350	1870	370	80[c]				
04 S	AC	5190	5	1307	155	88	3180	632	80	142
05 H	DE		15		12.2			61		15.4
05 S	DE	220	4	364	3.5	99	641	28	96	6.2
08 H	B	719	157	46.3	7.8	83	118	50.5	57	22.2
08 S	B	473	3	19	5.8	70	77	48	38	30
09 H	A	1570	1	1150	49	96	2120	278	87	134
09 S	A	2060	1	3150	26	99	6700	317	95	4
10 S	C	6820	4	1220	47	96	2800	1350	52	122
11 H	C	4960	106	894	79	91	2634	398	85	71
11 S	C	3420	4	2220	202	91	3670	650	82	60
12 S	B	89	3	25	b		46	b		
14 H	E	231	96	67	1.8	97	197	18	91	5.9
14 S	E	184	2	100	13	87	235	32	84	10
15 H	C		270				20,900	14,000	33	359
15 S	C	159	2	10,000	2,000	80	14,800	3680	75	47

(a) Number of composite samples from each station for each type of analysis.
(b) Wastewaters pass (sometimes with pretreatment) to a municipal treatment system.
(H)=Historical company data;   S= Field survey data

relatively low concentrations of organic matter, mostly in forms susceptible to treatment by either activated sludge or fixed-film reactors (stone or plastic media filter or biodiscs). A substantial part of the raw waste load is likely to be from facilities serving the needs of the workers and thus is similar to domestic sewage. By contrast, plants of the A and C subcategories produce wastewaters that may favor the growth of non-flocculating microbes.

During the survey program, 24-hour composite samples of influent and effluent of the wastewater treatment plant over a one to five day period were collected in order to verify the plants' historical performance data, as well as to provide a more complete wastewater analytical profile. The performance characteristics which were observed during the survey are presented in Table VII-3a.

Of the twenty-three treatment plants visited, at least seventeen treated multiple subcategory wastes. See Table VII-3a. Where subcategory A and/or C wastes are present with wastes of the other subcategories, they generally dominate the characteristics of the total waste stream because of their high concentrations and high RWL's.

Historical treatment plant data were reviewed in order to quantify treatment efficiencies which could then be applied to typical raw waste loads for each subcategory to develop effluent limitations and guidelines.

To identify the treatment efficiencies that should be applicable to this category, all of the treatment plant data for plants in this category (Table VII-3a) were analyzed. Only data from secondary biological treatment plants (activated sludge or equivalent technology) have been reviewed to indicate the level of treatment that is being achieved by current treatment plants in this industry.

Initially, the treatment plant performance data were evaluated to determine if there are different performance data for the different subcategories. The evaluation indicated that there are not sufficient historical data in the respective subcategories to warrant different removal efficiencies for each subcategory. Therefore, all of the historical treatment plant performance data are utilized to establish realistic treatment plant efficiencies that can be expected in this category. Data from thirteen plants have been used.

TABLE VII - 3b

12/6/76

Treatment Plant Performance Data

Plant	Subcat.	Flow cu m/day	N[a]	BOD (mg/1) Infl.	BOD (mg/1) Effl.	BOD (mg/1) % Rmvl.	COD (mg/1) Infl.	COD (mg/1) Effl.	COD (mg/1) % Rmvl.	TSS Effl. mg/1
16 H	BE	220	9	106	4.4	96				
17 S	BDE	2650	3	525	b		854	b		
18 S	D	284	2	748	59	92	1670	290	83	2
19 H	ACD	2350	360	2920	90	97				296
19 S	ACD	2850	2	3110	134	96	6800	680	90	210
20 S	A	946	4	1380	90	93	4380	1296	70	380
21 H	AC	4600	360			94[d]				147
21 S	AC	4600	1	1330	66	95	3260	1140	65	746
22 H	AC	5024	89	2536	178	93	5210	1300	75	197
22 S	AC	1623	1	2400	14	99	5270	178	97	19
23 H	BDE	345	94	21.2	1.4	93	105	68	35	18
23 S	BDE	332	2	11	2	82	98	67	32	
24 H	DE	329	105	195	12.3	94		58		28.5
24 S	DE	290	3	90	8	91	304	82	73	29
25 H	AC	1500	250		252	b		1487	b	937
25 S	AC	1015	2	795	280	65[b]	5300	4065	23[b]	—
26 H	ABCDE	4340	360	1240	93	92				177
26 S	ABCDE		1	1150	48	96	2540	211	92	153

(a) Number of composite samples from each station for each type of analysis.

(b) Wastewaters pass (sometimes with pretreatment) to a municipal treatment system.

(c) This estimate of efficiency is a minimum, because the effluent samples include an incremental load due to added cooling waters.

(d) 93% efficiency for treatment by the extended aeration activated sludge plant. Further treatment by a biofilter increases BOD removal to 96% and oxidation pond increases it to 99+%.

H = Historical company data; S = Field survey data

The legislative history indicates that exemplary plants shall be used to determine effluent limitations and where possible, the average of the best plants shall be used as a basis for such limitations. Because of the variation in the data, it was necessary to develop a reasonable procedure to identify the exemplary treatment plants.

The wastes from this category are organic and biological; they will exert an oxygen demand in a stream or a treatment plant. A key pollutant parameter is the parameter that measures the biological oxygen demand, i.e., BOD. The eleven exemplary plants have been identified from the following profile of biological treatment systems. Only those plants that had high treatment efficiencies and for which representative historical data are available (identified by asterisks in Table VII-3b) are used in developing the effluent limitations. Furthermore, this BOD_5 reduction (percent removal) could be accomplished by any number of treatment steps or any kind of wastewater treatment technology (physical, chemical, biological or any combination of these). Therefore, the identification of exemplary treatment plants was made on the basis of BOD_5 removals at the thirteen treatment plants. The historical BOD_5 data were arrayed in descending order of BOD_5 removal efficiencies, along with field survey data, (Table VII-3b) to delineate any distinctive pattern. The array indicated a natural break in the BOD_5 data with eleven of the thirteen treatment plants with historical data achieving 91 percent or greater BOD_5 removals. On this basis, it is appropriate to consider all of the plants achieving 91 percent BOD_5 removal or greater to be exemplary plants and to consider all of the historical data from these plants in determining reasonable treatment plant efficiencies to be used in establishing effluent limitations.

In keeping with the intent of the Act and the legislative history of basing effluent limitations on the average of the results from the best or exemplary plants, the reasonable treatment plant efficiencies are obtained by using the average of the BOD_5, COD and TSS data from the eleven exemplary plants identified in Table VII-3b.

On the basis of this analysis, six of the eleven exemplary plants will need to increase their BOD_5 performance and one will need to increase its COD removal.

From historical performance data for the chosen exemplary biological treatment plants, the following treatment efficiencies are selected as being applicable. The average efficiencies of the best treatment plants within a

TABLE VII-3c
ARRAY OF TREATMENT PLANT PERFORMANCE DATA

Plant No.	Subcategory	BOD_5 Removal (Percent)	COD Removal (Percent)	TSS in Effluent (mg/1)	Number of Samples
05	DE	99	96	6.2	4
09	A	99	95	4	1
19*	ACD	97	--	296	360
14*	E	97	91	6	96
10	C	96	52	122	4
16*	BE	96	--	---	9
24*	DE	94	--	28	105
21*	AC	94	--	147	360
02*	A	93	80	666	360
20	A	93	70	380	4
22*	AC	93	75	197	89
23*	BDE	93	35	18	94
18	D	92	83	2	2
26*	ABCDE	92	--	177	360
02*	C	91	79	362	360
11*	C	91	85	71	106
08	B	83	57	22	157
04	AC	80	--	--	350
15	C	80	75	47	2
25	AC	65	23	--	2

Average values for the eleven plants identified as exemplary:

BOD_5 Removal -- 94%

COD Removal -- 75%

Effluent TSS --
A, C 274
B, D, E 17.3

*Exemplary Plants (with historical data) subcategory have been 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 are as follows:

BOD5 removal	--	94%
COD removal	--	74%
Effluent TSS	--	274 mg/l for subcategories A & C
		17.3 mg/l for subcategories B, D & E

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% reduction to all subcategories is 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 are averaged and a variability factor of 3.0 has been applied. This variability factor represents the 99 percent probability to long term average ratio.

Although plant 02 is considered to be an exemplary plant for the purpose of calculating BOD5 and COD removal efficiencies, this plant does not qualify as an exemplary plant for TSS effluents. Additional review of this plant and other plants in subcategories A and C is indicated before a maximum value for the average of daily TSS values for any calendar month can be indicated. Furthermore, the maximum TSS value for any one day has been deferred for all subcategories until additional data has been collected, validated and statistically analyzed.

Since flocculator/clarifiers with polymer addition have been used in other industries to reduce TSS in activated sludge effluents, this process should also be applicable in the pharmaceutical industry as a technology capable of achieving low effluent TSS concentrations. However, since such use is not common in this industry, effluent TSS concentrations have not been based on the use of this technology.

In order to facilitate the economic analysis of the proposed effluent standards, model biological treatment systems have been developed for each subcategory. The prime design

Table VII -4

Summary of COD Carbon Isotherm Tests

Performed on Biological Treatment Plant Effluent

Pharmaceutical Industry

Plant No.	Subcategory	Carbon Exhaustion Rate		Highest Soluble BOD Removal Observed (%)
		lbs. COD Removed / lb. Carbon	lbs. Carbon / 1000 gal.	
19	A&C$_1$	1.22	2.98	84
08	B	Test Not Conclusive		
14	E	Test Not Conclusive		
11	C$_1$	0.45	11.3	71
20	A	0.40	5.4	81
05	D&E	Test Not Conclusive		

Table VII -5

Summary of BOD5 Carbon Isotherm Tests

Performed On Biological Treatment Plant Effluent

Pharmaceutical Industry

Plant No.	Subcategory	Carbon Exhaustion Rate		Highest Soluble BOD Removal Observed
		lbs. BOD5 Removed / lb. Carbon	lbs. Carbon / 1000 gal.	(%)
19	A&C_1	0.021	8.74	77
08	B	0.011	3.79	80
14	E	Test not conclusive		
11	C_1	Test not conclusive		
20	A	Test not conclusive		
05	D&E	Test not conclusive		

Table VII -6

Summary of TOC Carbon Isotherm Tests

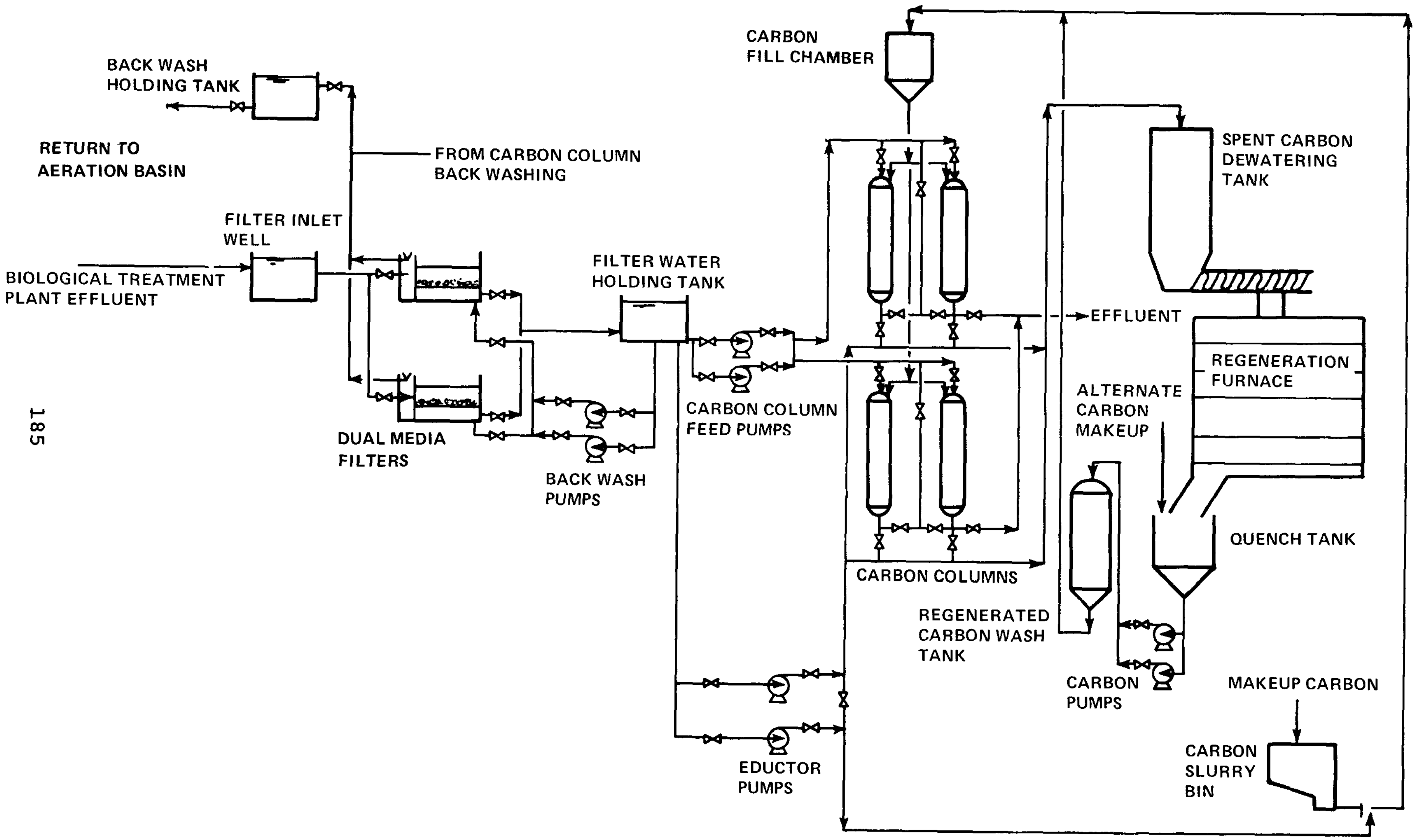
Performed on Biological Treatment Plant Effluent

Pharmaceutical Industry

Plant No.	Subcategory	Carbon Exhaustion Rate		Highest Soluble TOC Removal Observed (%)
		lbs. TOC Removed / lb. Carbon	lbs. Carbon / 1000 gal.	
11	C	0.68	2.8	83
20	A	0.25	2.3	77
05	D&E	Test not conclusive		

FIGURE VII-2

Activated Carbon Adsorption
Schematic



parameter in BPT and NSPS treatment models is BOD5 removal, whereas COD and TSS removal are considered as secondary design parameters. In the case of BAT treatment models, COD and TSS are the prime design parameters.

The use of biological treatment models for BPT is done only to facilitate the economic analysis and is not to be thought of as the only technology capable of meeting the effluent limitations, guidelines and standards of performance presented in this report.

Activated Carbon Adsorption

No activated carbon treatment systems were observed during the survey. Consequently, to investigate the possibilities of using activated carbon technology on the effluents from biological treatment plants treating pharmaceutical wastewaters, a series of carbon isotherms were run at standard conditions using a contact time of 30 minutes. The results of the carbon isotherm tests are presented in Tables VII-4, VII-5 and VII-6. Average performance values for subcategories A and C are as follows:

Parameter	Carbon Exhaustion Rate (lbs removed/lb carbon)	Highest Pollutant Removal Observed (percent)
COD	0.69	80
BOD5	0.02	77
TOC	0.48	80

Due to the limited number of tests, the number of inconclusive carbon isotherm (equilibrium) tests and the high variability of subcategory C wastes, it does not appear practical at this time to transfer this technology from other related industries based on this preliminary testing and to set effluent limitations on the possible use of this technology. However, for completeness, a schematic for an activated carbon adsorption system is shown in Figure VII-2.

Since pilot plant continuous column tests on a range of chemical synthesis wastes would be necessary to demonstrate activated carbon performance on these wastes, fixed film biological treatment (trickling filters or biodiscs) have been chosen to meet the BAT limits in subcategories A and C. Each tertiary biological reactor and its associated final clarifier follow the biological secondary process (activated sludge or biological filter system) and precede multi-media filtration followed by final effluent chlorination. Where plant sites include large areas of vacant flat land, an

TABLE VII - 7

RESULTS OF STUDIES OF FILTRATION OF
EFFLUENT FROM SECONDARY BIOLOGICAL TREATMENT *

Location	Type of Filter	Infl. Source	Media	Media Size mm	Bed Depth inches	Hydr. Loading gpm/ft^2	Suspended Solids In mg/l	Suspended Solids Out mg/l	Suspended Solids Removal %	Run Length (Hours)
Hanover Park Illinois	Pressure downflow	Act. sl.	Coal	1.4 - 1.8	24 **	2	16	7	56	90
			Sand	0.8 - 1.0	12 **	4	15	5	67	15
						6	16	6	62	22
						8	13	6	54	31
						10	18	8	55	12
Bedford Twp. Michigan	Pressure downflow	Act. sl.	Multi-media	--	--	--	15	3	80	15
Ann Arbor Michigan	Pressure downflow	Act. sl.	Multi-media	--	--	6	42	5	88	--
State College Pa.	Pressure	Act. sl.	Sand	--	84	3-12	6	1	85	6
Average of eight removal efficiencies -									68%	

* From Table 9 - 1, Process Design Manual for Suspended Solids Removal EPA 625/1-75-003 - Jan. 1975.

** Total bed depth = 36 inches

oxidation pond holding a few days of average plant flow can be substituted for the final biological reactor and clarifier with similar results. In freezing climates, the final oxidation device must be chosen after proper consideration of mechanical problems caused by ice accumulations.

BOD removal of 80% is used in sizing biological reactors for the tertiary treatment steps in subcategories A and C. This efficiency takes into account the increased difficulty in biologically oxidizing a waste which has already undergone secondary treatment, as compared with a waste which has received only primary treatment.

Multi-Media Filtration

While multi-media filtration for final effluent polishing was not observed during the plant survey, the removal of suspended matter by filtration is subject to transfer of technology from water and waste treatment practice in a wide variety of process industries.

Results of multi-media and pressure sand filtration tests reported in Table 9-1 of EPA "Process Design Manual for Suspended Solids Removal" are briefed in Table VII-7 to show filter performance using secondary sewage effluent. The average of eight tests at various loading rates shows 68% TSS removal. Because pharmaceutical waste effluent, particularly in the C subcategory, may contain finely divided suspended matter, a 60% reduction of TSS by filtration has been chosen.

The effluent limitations that must be achieved by all plants by 1 July, 1977 through the application of the Best Practicable Control Technology Currently Available (BPT) are based upon an average of the best performance achievements of existing exemplary plants.

When multi-media filtration is used, as in the BAT and NSPS models, reductions in BOD and COD may occur, due to partial removal of organic matter comprising the TSS. Such reductions in concentration are related to TSS removal by factors to be applied to the reduction of TSS concentration by filtration.

These factors have been developed from theoretical oxygen requirements needed to oxidize assorted organic matter found in activated sludge solids. (See development of supporting logic in Section X.) The factors are 0.5 times TSS removed (for BOD_5) and 1.2 times TSS removed (for COD).

SECTION VIII

COST, ENERGY, AND NON-WATER QUALITY ASPECTS

General

In order to evaluate the economic impact of treatment on a uniform basis, end-of-pipe treatment models which will provide the desired level of treatment were proposed for each industrial subcategory. In-plant control measures have not been evaluated because the cost, energy and non-water quality aspects of in-plant controls are intimately related to the specific processes for which they are developed. Although there are general cost and energy requirements for equipment items, these correlations are usually expressed in terms of specific design parameters. Such parameters are related to the production rate and other specific considerations at a particular production site.

In the manufacture of a single product there is a wide variety of process plant sizes and unit operations. Many detailed designs might be required to develop a meaningful understanding of the economic impact of process modifications. Such a development is really not necessary, however, because the end-of-pipe models are capable of attaining the recommended effluent limitations at the RWL's within the subcategories of this industry.

The major non-water quality consideration associated with in-process control measures is the means of ultimate disposal of wastes. As the volume of the process RWL is reduced, alternative disposal techniques such as incineration, pyrolysis and evaporation become more feasible. Recent regulations tend to limit the use of ocean discharge and deep-well injection because of the potential long-term detrimental effects associated with these disposal procedures. Incineration and evaporation are viable alternatives for concentrated waste streams. Considerations involving air pollution and auxiliary fuel requirements, depending on the heating value of the waste, must be evaluated individually for each situation.

Other non-water quality aspects such as noise levels will not be perceptibly affected by the proposed wastewater treatment systems. Most pharmaceutical plants can generate fairly high noise levels. (85-95 decibels within the battery limits because of equipment such as pumps, compressors, steam jets, flare stacks, etc.) Equipment associated with in-process and end-of-pipe control systems would not add significantly to these noise levels.

Extensive annual and capital cost estimates have been prepared for the end-of-pipe treatment models for this industry to evaluate the economic impact of the proposed effluent limitations and guidelines. The capital costs were generated at a ±25% confidence level as follows. Installed equipment costs, exclusive of site preparation and certain other ancillary work, were obtained by quotations from vendors and verified from in-house experience. To the total of these costs were added certain percentages to cover the missing items of work. These are:

Piping	at	20%
Electrical	at	14%
Instrumentation	at	8%
Site preparation	at	6%

Addition of the cost of the land (at $15,000/acre) yielded a nominal in place cost for the plant. Actual capital cost was then computed by adding a further 30% for engineering and contingencies.

The above calculations were made using equipment appropriately sized for the hydraulic capacity and the RWL developed for each subcategory. In addition, the data were extended to higher and lower hydraulic capacities appropriate for each subcategory.

Cost data are presented in Section VIII and Supplement A.

Annual costs are computed using the following cost basis:

Item	Cost Allocation
Capital Recovery plus Return	10 yrs at 10 percent
Operations and Maintenance	Includes labor and supervision, chemicals, sludge hauling and disposal, insurance and taxes (computed at 3 percent of the capital cost), and maintenance (computed at 5 percent of the capital cost).
Energy and Power	Based on $0.03/kw hr for electrical power.

The 10-year period used for capital recovery is that which is presently acceptable under current Internal Revenue

Service regulations pertaining to industrial pollution control equipment.

The following is a qualitative as well as a quantitative discussion of the possible effects that variations in treatment technology or design criteria could have on the total capital costs and annual costs.

Technology or Design Criteria	Capital Cost Differential
1. Use aerated lagoons and sludge de-watering lagoons in place of the proposed treatment system.	1. The cost reduction could be 20 to 40 percent of the proposed figures.
2. Use earthen basins with a plastic liner in place of reinforced concrete construction and floating aerators.	2. Cost reduction could be 20 to 30 percent of the total cost.
3. Place all treatment tankage above grade to minimize excavation, especially if a pumping station is required in any case. Use all-steel tankage to minimize capital cost.	3. Cost savings would depend on the individual situation.
4. Minimize flows and maximize concentrations through extensive in-plant recovery and water conservation, so that other treatment technologies, e.g., incineration, may be economically competitive.	4. Cost differential would depend on a number of items, e.g., age of plant, accessibility to process piping, local air pollution standards, etc.

Effects of Treatment Plant Size and RWL upon Capital Costs

Waste treatment plant capacities within each subcategory vary over wide ranges depending upon the production capacities of the operation served. Annual costs in this document have been developed for models which represent the average capacities and average raw waste loads of waste treatment plants considered exemplary in each subcategory. Because capital costs vary with capacity and with raw waste load in a non-liner relationship, each model plant has been scaled up and down to cover the capacity range of plants reviewed, and to accommodate raw BOD_5 and TSS loads of 0.5

TABLE VIII - 1

BPT, NSPS and BAT Waste Treatment Cost Models - Pharmaceutical Industry

Level	Component	Subcategory A	B	C	D	E
BPT	Equalization Facilities	with A.B.	separate	with A.B.	separate	separate
	Neutralization Facilities	X		X		
	Primary Clarifiers (2)	X		X		
	Aeration Facilities (A.B.)	X (4 days)	X	X (4 days)	X	X
	Nutrient Addition Fac.	X	X	X	X	X
	Secondary Clarifiers (2)	X	X	X	X	X
	Flow Measurement & Monitoring	X	X	X	X	X
	Sludge Thickening Facilities	X		X		
	Aerobic Sludge Digestion	X	X	X	X	X
	Vacuum Filtration (Sludge)	X		X	X	
	Sludge to Landfill or farming	X (dry)	X (wet)	X (dry)	X (dry)	X (wet)
	Trickling Filter			X(1st stage)		
	Final Clarifiers (2)			X		
	Diversion Basin	X		X		
	Polishing Pond	X		X		
	Effluent Chlorination	X	X	X	X	X
NSPS	Multi-Media Filtration (after BPT)	X	X	X	X	X
BAT	Trickling Filter	X		X(2nd stage)		
	Final Clarifiers (2)	X				
	Multi-Media Filtration (all following BPT Treatment)	X	X	X	X	X

and 2 times the averages. These relationships have been expressed as multi-dimensional equations which yield estimated capital costs for various combinations of hydraulic capacity, BOD5 and TSS for each subcategory. These equations for BPT levels of treatment are presented in Table VIII-4. Annual costs have been detailed only for the five average capacity models having average raw waste loads, as shown in Tables VIII 7 through 12.

Original cost data were computed in terms of 1972 dollars, which corresponds to an Engineering News Record (ENR) Construction Index of 1780. Costs have been updated in 1976 by applying factors from 1.3 to 1.6, depending upon the relative proportions of construction materials, labor and mechanical equipment involved in each plant component, designed, installed and ready to operate. Final capital costs of the models are expressed in terms of May 1976 dollars, when the ENR construction index was 2330. See Table VIII-4 for tabulation of ENR indices.

The design considerations for the model treatment systems (namely, the influent RWL) have been selected so that they represent the average RWL expected within each subcategory. This generated cost data which would be representative when applied to most of the RWL data within a particular subcategory. Activated sludge is proposed in Section VII as the BPT treatment system for subcategories A, B, C, D and E supplemented in the subcategory C model by tertiary trickling filtration with final clarification. The activated sludge plant designs have been varied to generate cost-effectiveness data for each subcategory. BPT treatment plus multi-media filtration is proposed in Section VII as NSPS treatment for subcategories A, B, C, D and E. BAT treatment is the same as NSPS treatment for all subcategories except that trickling filtration and final clarification follow activated sludge treatment in the subcategory A model.

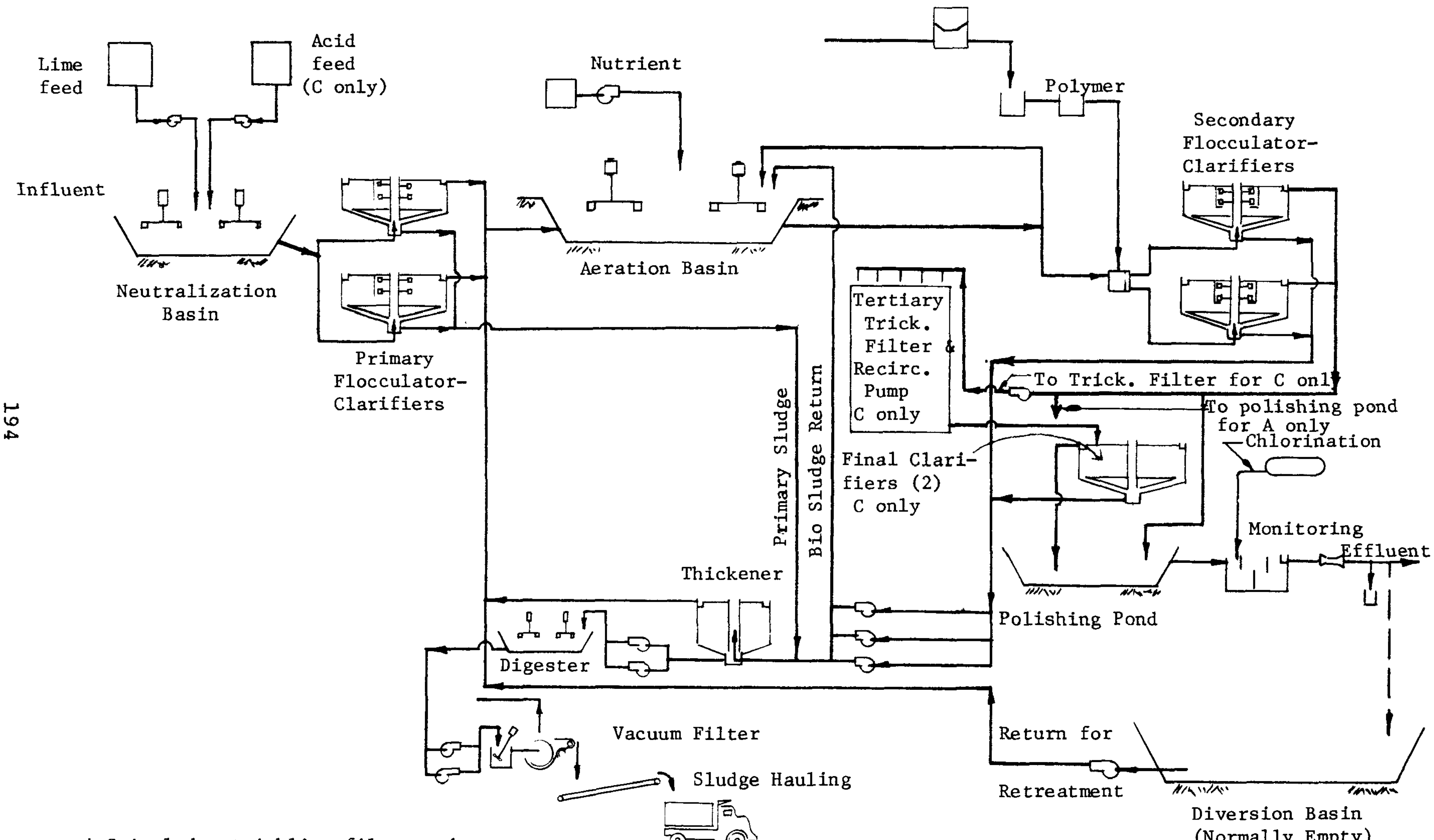
<u>BPT Cost Model</u>

General flow diagrams for the BPT wastewater treatment facilities for subcategories A, B, C, D and E are shown in Figures VIII-1 and VIII-2. Specific unit processes, applicable to each subcategory model treatment facility, are listed in Table VIII-1. A summary of the general design basis is presented in Table VIII-2.

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

FIGURE VIII - 1

Pharmaceutical Industry
BPT Cost Model - Subcategories A and C*



* C includes trickling filter and final clarifiers after act. sludge treatment
"A" secondary effluent passes directly to polishing pond.

Fig. VIII - 2

Pharmaceutical Industry
BPT Cost Model - Subcategories B, D and E

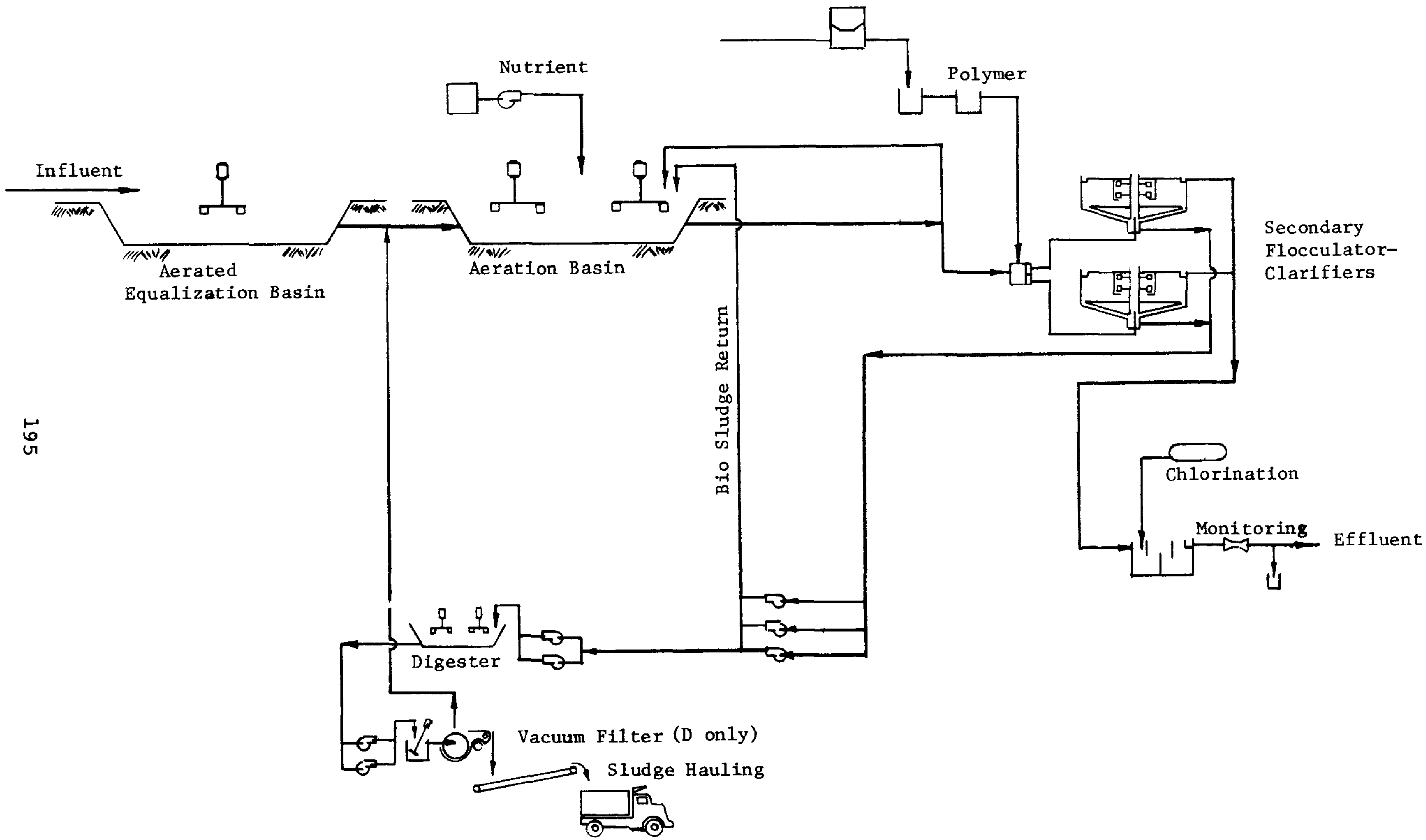


Table VIII- 2a

BPT Cost Model Design Summary

Pharmaceutical Industry

Subcategories A,B,C, D and E

Treatment System Hydraulic Loading
(Average design capacities)

Subcategory	Hydraulic Loading (cu m/day)	Hydraulic Loading (gpd)
A	1,162	307,000
B	75.7	20,000
C	3,058	808,000
D	265	70,000
E	113.6	30,000

Equalization

For plants with less than 24-hour/day and 7 day/week production, a minimum aerated holding time of 1.5 days is provided, with continuous discharge from the equalization basin over 24 hours. For plants with less than 24-hour/day and 5 days/week production, 2-day equalization is provided. Discharge from the basin will be continuous over the seven days. For plants in subcategories A and C, which typically operate 7 days per week, 24 hours per day, equalization is provided within the four-day aeration basins, which are arranged for optional series or parallel flow. Mixing of acids and alkaline wastes within the four-day basins, together with the large volume of diluting material, make corrosion resistant linings un-necessary in A and C basins. Because extremes of pH are not expected in B, D or E wastes, plain concrete walls and bottoms are adequate in B, D and E equalization basins.

Neutralization

The two-stage neutralization basin is sized on the basis of an average detention time of 20 minutes. The size of lime and acid handling facilities is determined according to acidity/alkalinity data collected during the survey. Bulk lime-storage facilities (18 kkg or 20 tons) or bag

Table VIII- 2b

storage is provided, depending on plant size. Sulfuric acid storage is either by 0.21 m^3 (55-gallon) drums or in carbon-steel tanks. Lime or acid addition is controlled by two pH probes, one in each basin. The lime slurry is added to the neutralization basin from a volumetric feeder. Acid is supplied by positive displacement metering pumps.

Primary Flocculator-Clarifiers

Primary flocculator-clarifiers are provided only for subcategories A and C, in which raw influent TSS typically exceed 200 mg/l. Clarifiers are circular, with design overflow rates of 24.4 $m^3/day/m^2$ (600 gpd/sq ft) and with sidewater depths of 2.1 to 4.0 meters (7 to 13 ft) depending on plant size. Units are furnished in duplicate, with each handling one half the total flow in parallel.

Nutrient Addition

Facilities are provided for the addition of phosphoric acid and anhydrous ammonia to the biological system in order to maintain the ratio of BOD:N:P at 100:5:1.

Aeration Basin

Subcategory A and C aeration basins are designed to retain four days average flow, with cells arranged for parallel or series flow, permitting optional equalization in all or part of the total capacity. Sizes of B, D and E aeration basins are based on historic treatability data collected during the survey. Mechanical surface aerators are provided in the aeration basin.
Aerators were selected on the basis of the following:

Oxygen Utilization:	1.0 kg O_2/kg BOD removed
α (factor to relate oxygen transfer in wastewater to oxygen transfer in de-aerated fresh water)	.75 x .9 = .675
Oxygen Transfer	1.6 kg O_2/hr/shaft HP at 20°C and zero D.O. in tap water
Motor Efficiency	85 percent
Minimum Basin D.O.	2 mg/L
Minimum Number of Aerators	2

Oxygen is monitored in the basins using D.O. probes.

Table VIII -2c

Secondary Flocculator-Clarifiers

The design basis for secondary flocculator-clarifiers is the same as for primary units, with an overflow rate of 24.4 $m^3/day/m^2$ (600 gpd/sq ft). Feed facilities for polymer addition are provided. Clarifiers are furnished in duplicate, with adjustable sludge wasting facilities on the underflow return.

Sludge Thickener

The thickeners provided was designed on the basis of a solids loading of 29.3 $kg/m^2/day$ (6 lbs/sq ft/day). Thickeners are not included for subcategories B, D, and E.

Aerobic Digester

The size of the aerobic digester is based on a hydraulic detention time of 20 days. The size of the aerator-mixers was based on an oxygen requirements of 1.6 kg O_2/kg VSS destroyed and a mixing requirement of 0.044 HP/m^3 (165 HP/million gallons) of digester volume.

Vacuum Filtration

The size of the vacuum filters was based on a cake yield of 9.8 $kg/m^2/hr$ (2 lbs/sq ft/hr) for biological sludge, and 19.5 $kg/m^2/hr$ (4 lbs/sq ft/hr) for combined primary and biological sludge. Maximum running times of 16 hours for large plants and 8 hours for small plants are used. The polymer system was sized to deliver up to 9.1 kg (20 lbs) of polymer per ton of dry solids.

Final Sludge Disposal

For all plants, sludge is disposed of at a sanitary landfill. Sludge from B and E plants is hauled without dewatering, and could be alternately spread on nearby agricultural land.

Design Philosophy

Individual units within the plant have been sized and arranged so that they may be taken out of operation for maintenance without seriously disrupting the operation of the plant. Plants have been designed with maximum flexibility by providing a choice of operating options.

Diversion Basins

Empty earthen basins to hold 2 days average flow are provided for A and C plants, to receive effluent which exceeds the maximum permissible discharge limitations. A manually controlled pump is provided to return the unacceptable effluent to an appropriate process component for re-treatment. In emergencies these basins could accept temporary overloads or inadequately treated wastes at any stage of treatment.

Table VIII - 2d

Tertiary Treatment

To achieve the required BOD and COD reductions in the often complex wastes of Subcategory C, a fixed film oxidizing reactor with final clarification is used following the activated sludge process. In the C model a lightly loaded (.30 kg BOD/day per cu m) trickling filter, 3.7 meters deep, is included, to promote direct contact oxidation of non-flocculating growths, followed by parallel final clarifiers operating at 24.4 $m^3/day/m^2$. BPT Models for other subcategories do not include tertiary treatment, although it is shown in the A Model at a higher level of treatment (BAT - to be achieved in 1983).

Polishing Ponds

Primarily for quiescent settling of persistent TSS, deep ponds of up to 2 days detention are included in the A and C models. Accumulated solids are to be removed by pumping from multiple bottom draw-offs.

Effluent Chlorination

Since human wastes are normally present, all models include manually adjusted solution feed gas chlorination, with 30 minute contact time at average flow, to control pathogens.

TABLE VIII - 3

Typical BPT End of Pipe Waste Treatment Requirements

Pharmaceutical Industry - Subcategories A, B, C, D, E

	Examples Used in Models				BOD Removal			COD Removal			TSS
Sub-category	Product kkg/day	Flow cu m/day	Infl. BOD mg/l	Infl. COD mg/l	%	Effl. mg/l	Effl. kg/day	%	Effl. mg/l	Effl. kg/day	Effl. Limit mg/l
A	1.54×10^3	1162	4400	10,120	90	440	511	74	2631	3057	105
B	$.236 \times 10^3$	76	225	653	90	23	1.7	74	170	12.9	52
C	18.75×10^3	3058	4560	10,488	90	456	1395	74	2727	8339	105
D	8.8×10^3	265	659	1911	90	66	175	74	497	132	52
E	—*	114	210	609	90	21	2.4	74	158	18	52

* No tangible product in research type facilities

Rationale for Selection of Unit Treatment Processes

Subcategories A, B, C, D and E

Equalization facilities are provided in order to minimize 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 larger 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 wastewater 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 wastes in subcategories B, D and E.

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.

The subcategory C model includes trickling filtration and final clarification following the secondary biological treatment to remove the additional BOD_5 needed to achieve 94% BOD_5 reductions.

For all subcategories, a single-stage activated sludge process has been selected for the model treatment systems because of its demonstrated ability to efficiently treat pharmaceutical wastes.

However, the single stage activated sludge treatment in the subcategory C model is followed by a fixed film oxidation reactor (trickling filter) and final clarifiers for the following reasons:

TABLE VIII - 4
ENGINEERING NEWS - RECORD (ENR) INDICES

YEAR	Jan.	Feb.	Mar.	Apr.	May	June	July	Aug.	Sept.	Oct.	Nov.	Dec.	ANNUAL INDEX
1964	917.94	920.40	922.41	926.27	929.74	935.42	944.97	947.92	947.36	947.74	948.25	948.12	936.38
1965	947.56	957.43	957.70	957.43	957.92	969.34	977.08	984.16	986.29	986.18	985.83	987.74	971.22
1966	987.94	997.43	998.32	1006.06	1014.03	1028.65	1030.56	1033.37	1033.72	1032.40	1032.71	1033.71	1019.08
1967	1039.05	1040.67	1043.31	1043.54	1059.20	1067.88	1078.45	1089.14	1092.22	1096.22	1096.74	1098.39	1070.40
1968	1107.37	1113.63	1117.15	1123.73	1140.31	1152.78	1159.04	1169.68	1184.20	1189.08	1190.73	1200.82	1154.04
1969	1216.13	1229.56	1238.14	1248.85	1258.33	1284.90	1282.77	1292.20	1285.29	1299.31	1305.23	1304.76	1270.46
1970	1308.61	1310.90	1314.45	1329.21	1345.36	1368.60	1413.91	1418.44	1422.54	1433.64	1445.13	1445.08	1379.66
1971	1465.07	1466.85	1494.06	1511.49	1542.95	1575.05	1597.8	1614.78	1639.64	1642.59	1644.06	1654.75	1570.57
1972				1706.89	1735.15	1760.78	1771.56	1776.80	1785.29	1793.75	1807.60	1815.86	1752.23
1973	1837.87	1849.70	1858.96	1873.62	1880.26	1896.21	1901.24	1920.79	1929.03	1933.19	1934.85	1938.84	1896.74
1974	1939.47	1939.74	1940.19	1961.25	1960.88	1993.47	2041.36	2075.49	2088.82	2094.74	2094.06	2098.26	2019.31
1975	2103.00	2127.72	2127.65	2135.03	2163.72	2205.00	2247.65	2274.3	2275.34	2293.03	2291.65	2297.15	2211.77
1976	2300.42	2309.97	2317.14	2327.33	2356.76	2409.51	2413.60	2444.94	2468.38	2478.22			
1977													
1978													
1979													
1980													
1981													

Source: Engineering News-Record, McGraw-Hill,
Base Year 1913=100

Treatment Optimization Research Program
Advanced Waste Treatment Research Laboratory

Table VIII-5

BAT Cost Model Design Summary

Pharmaceutical Industry

Subcategories A, B, C, D, and E

Trickling Filter (1 stage in Plant A. Add 2nd stage in Plant C)

The tertiary trickling filter in the subcategory A plant is a 3.66 m (12 ft) deep rock filter designed for 75% BOD removal at 0.297 kg BOD per day per cubic meter (0.5 lb/cu yd) of 2" to 4" rock. Recirculation pumps for 2 to 1 recirculation are provided, but normal recirculation is 1 to 1. It is recognized that BOD removal becomes more difficult as the degree of prior treatment increases.

Final Clarifiers (In plant A only)

Clarifiers following the tertiary trickling filter are furnished as two parallel units, each designed for 24.4 $m^3/day/m^2$ (600 gpd/sq ft) overflow rate, as in the primary and secondary clarifiers.

Multi-Media Filtration (In plants A,B,C,D,and E)

Multiple pressure filters are provided, sized for average hydraulic loading of 0.122 $m^3/min/m^2$ (3 gpm/sq ft). The filter media are 61 cm (24") of anthracite (1 mm effective size) over 30.5 cm (12") of sand (0.4 to 0.5 mm effective size).

Backwash Facilities (In plants A,B,C,D and E)

Backwash facilities provide rates up to 0.813 $m^3/min/m^2$ (20 gpm/sq ft) and a total backwash cycle up to 10 min. duration. Backwash water is taken from the chlorine contact chamber and backwash waste is directed to the aeration basin, to avoid hydraulic surging of clarifiers.

Placement in System

The tertiary trickling filter and final clarifiers in the A plant are to follow the BPT secondary clarifier. The multi-media filters are to follow the polishing ponds in A and C plants, and the secondary clarifiers of B, D, and E plants, with suitable flow regulation of the filter influent. In the C model a second stage trickling filter is inserted in the BPT system between 1st stage trickling filter and final clarifier.

TABLE VIII - 6

NSPS Treatment System Design Summary

Pharmaceutical Industry

Subcategories A,B,C,D and E

Multi-Media Filtration

Multiple pressure filters are provided, sized for average hydraulic loading of 0.122 $m^3/min/m^2$ (3 gpm/sq ft). The filter media are 61 cm (24") of anthracite (1 mm effective size) over 30.5 cm (12") of sand (0.4 to 0.5 mm effective size.).

Backwash Facilities

Backwash facilities provide rates up to 0.813 $m^3/min/m^2$ (20 gpm/sq ft) and a total backwash cycle up to 10 min. duration. Backwash water is taken from the chlorine contact chamber and backwash waste is directed to the aeration basin, to avoid hydraulic surging of clarifiers.

Placement in system

The multi-media filters are to be inserted between the secondary clarifiers and effluent monitoring facilities in the BPT systems of subcategories B, D & E ahead of final chlorination.
In subcategories A and C filters follow the polishing pond, which provides filter influent storage.

1. Subcategory C wastes and combinations of subcategories A and C wastes produce RWL's significantly higher than RWL's in the other subcategories.

2. Some components of subcategory C wastes tend to form non-flocculating organisms which resist gravity separation and hence hinder sludge recirculation in the activated sludge process.

3. Fixed film reactors provide intimate contact between organisms and load in a manner which promotes oxidation of single cell non-flocculating organisms.

4. Conditions are highly favorable for nitrification of ammonia which is often present in subcategory C wastes.

All treatment processes require sludge disposal. In the biological process, for every pound of BOD removed from a wastewater, approximately 0.6 pound of TSS (biological solids) is produced which must be removed from the system.

BAT Cost Model

The BAT treatment model used for economic evaluation of the proposed limitations for subcategory A includes the BPT treatment model followed by trickling filtration, final clarification and multi-media filtration. In subcategory C the BAT model consists of adding multi-media filtration to the BPT system, which already includes tertiary trickling filtration and final clarification. Typical flow diagrams for the selected model treatment facilities are shown in Figures VIII-3 series. A summary of the general design basis is presented in Table VIII-5. Treatment facilities for subcategories B, D and E exclude the final trickling filter and clarifier, but include multi-media filtration.

NSPS Cost Model

The NSPS end-of-pipe treatment model used for economic evaluation of the proposed limitations for subcategories A, B, C, D and E includes the BPT treatment model followed by multi-media filtration. A typical flow diagram for the selected model treatment facilities is shown in Figure VIII-4. A summary of the design basis is presented in Table VIII-6.

FIGURE VIII - 3 a

PHARMACEUTICAL INDUSTRY
BAT COST MODEL
SUBCATEGORIES A & C

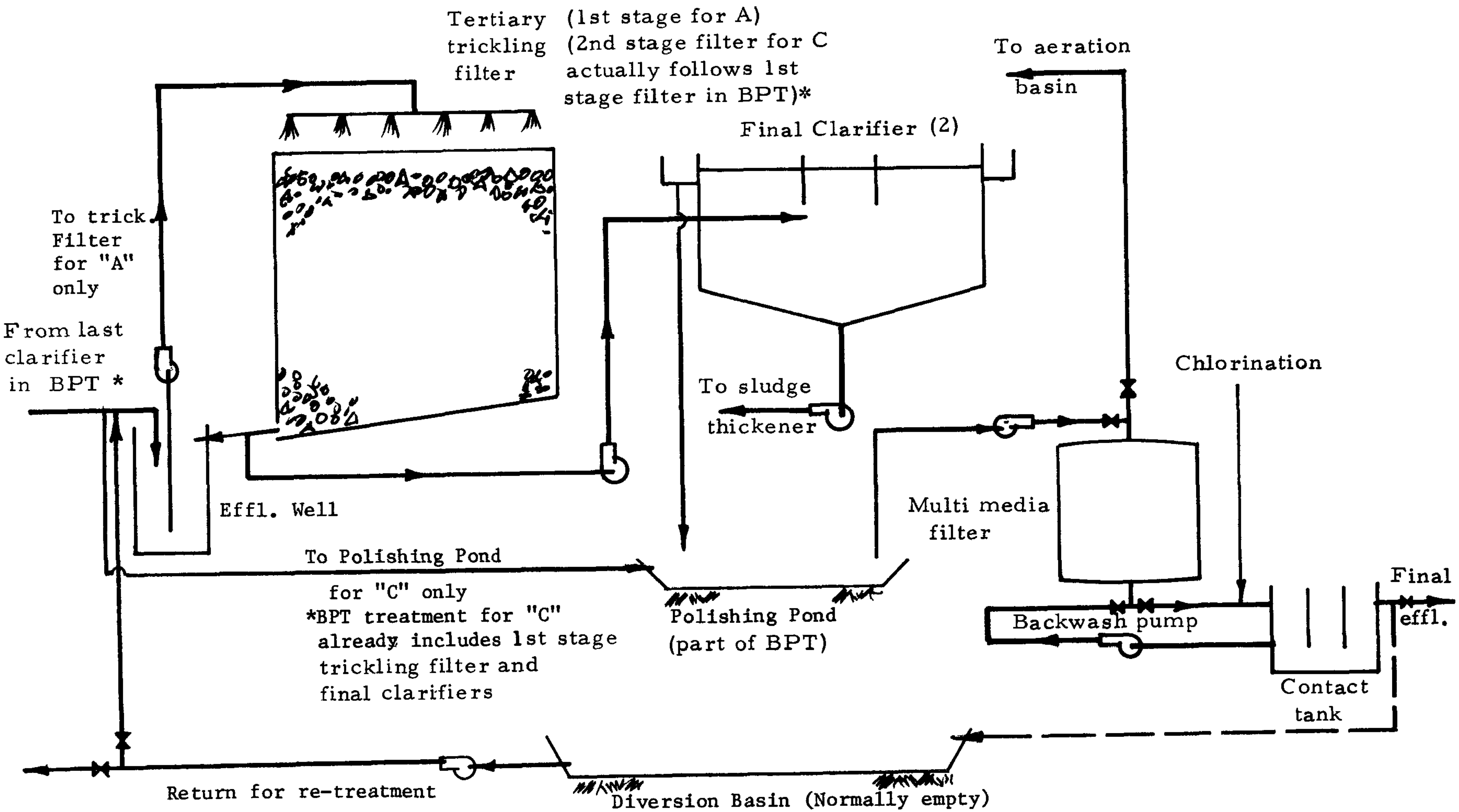


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Fig. VIII - 3 b

Pharmaceutical Industry
BAT Cost Model - Subcategories B, D, E

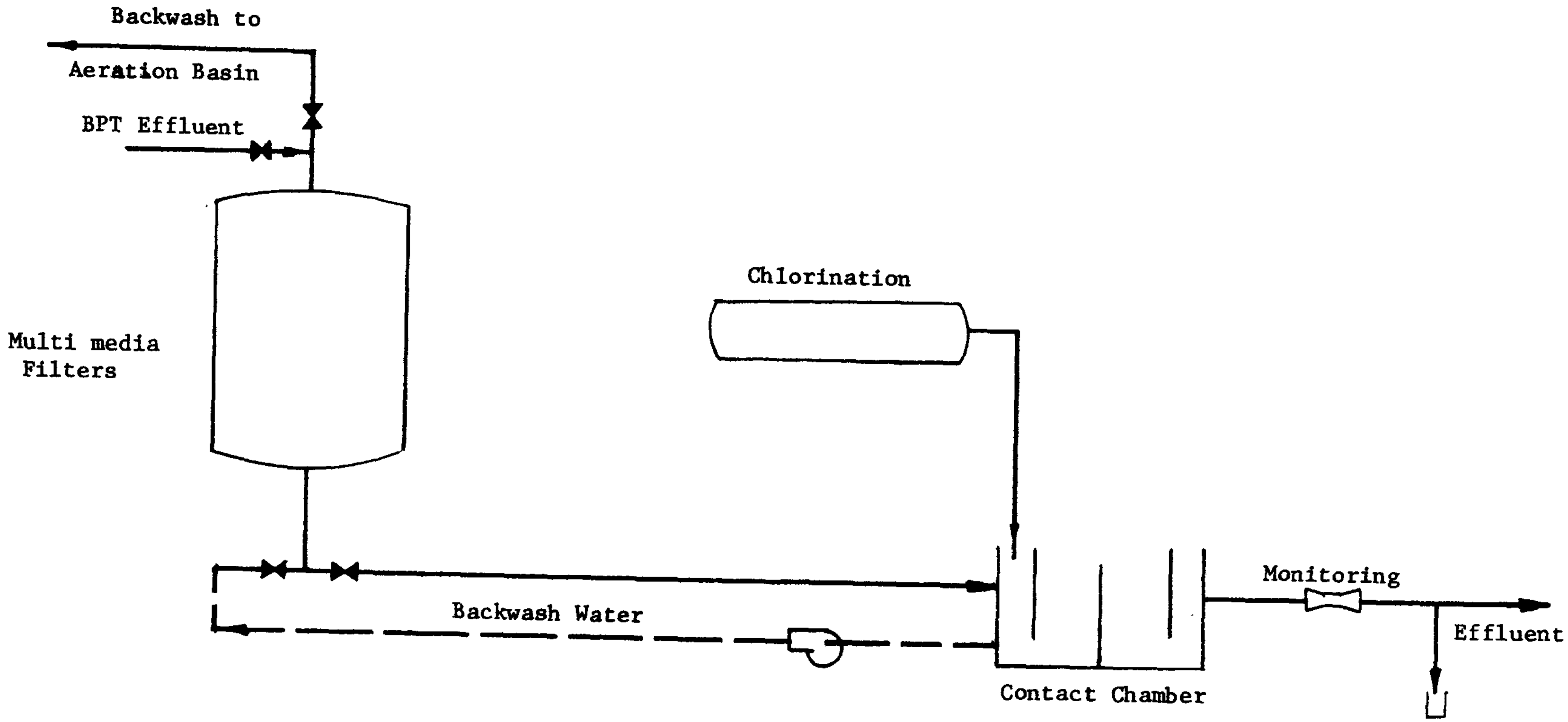
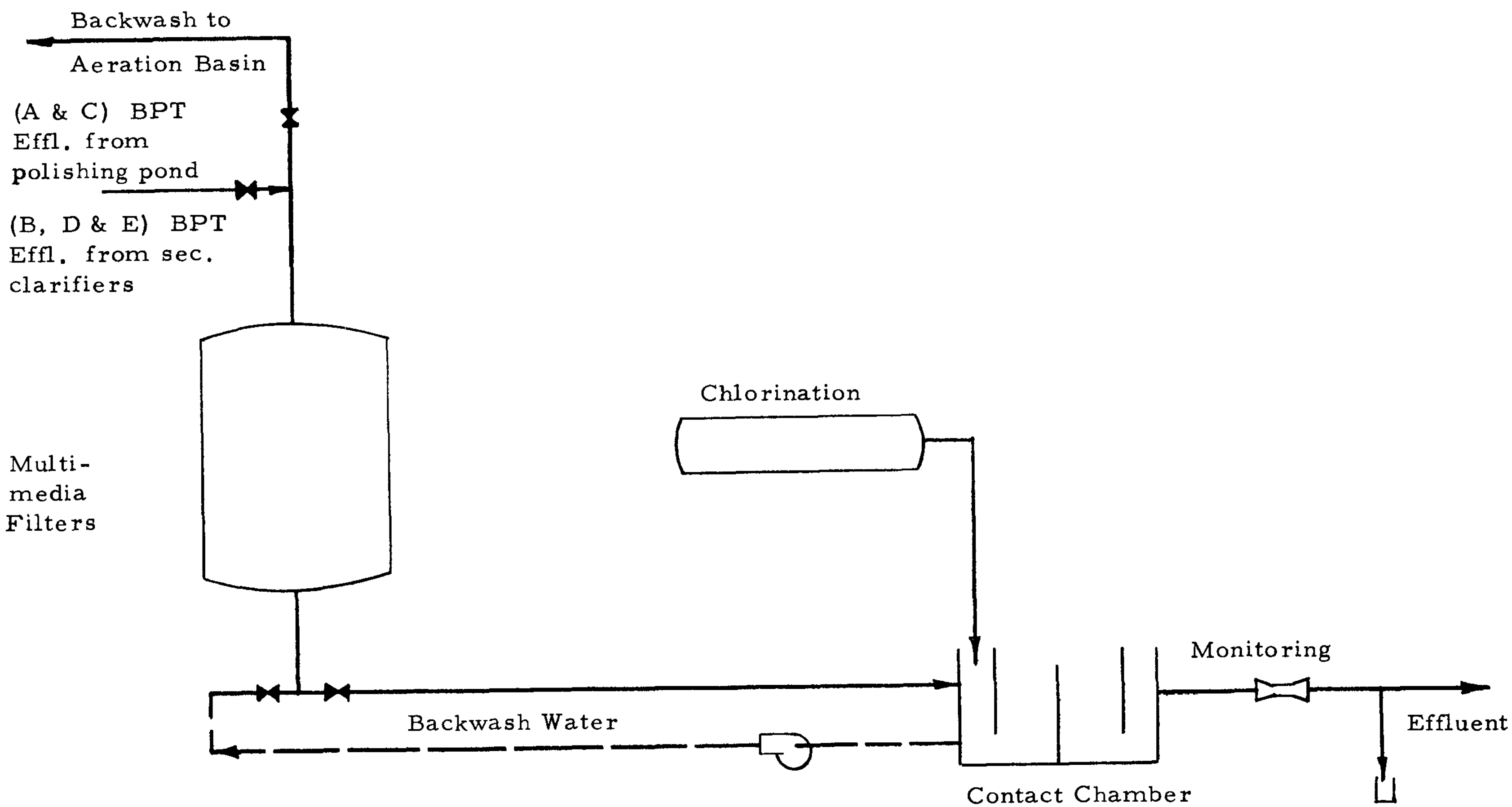


FIGURE VIII-4

NSPS COST MODEL

SUBCATEGORIES A, B, C, D, AND E



Cost

Capital and annual cost data have been prepared for each of these proposed treatment systems in accordance with the considerations outlined in the General part of this section. The cost requirements for implementing the proposed effluent standards are presented in Tables VIII-7 through VIII-12. Summaries of capital costs for the various subcategories are presented in Tables VIII-14 through VIII-18.

A discussion of the possible effects that variations in treatment technology or design criteria could have on capital and annual costs is presented in the preceding General section.

Wastes from certain plants within subcategories A and C may be amenable to sludge incineration because of the large quantities of sludge produced. However, if additional energy in the form of auxiliary boiler fuel is required for incineration this alternative is discouraged. Sludge incineration costs were not evaluated for those specific cases in subcategories A and C, because the particular economics depend to a large degree on the accessibility of a sanitary landfill and the relative associated haul costs. Use of the sludge for fertilizer is a viable alternative in some situations (Plant 21).

Before comparing the variations in costs between each subcategory, the following discussion is presented to help understand the complexities involved in evaluating cost-effectiveness data. Every treatment system is composed of units whose design basis is primarily hydraulically dependent, organically dependent, or a combination of the two factors.

The following is a list of the unit processes employed and a breakdown of the design basis:

Hydraulically Dependent	Organically Dependent	Hydraulically and Organically Dependent
Pump station	Thickener	Aeration basin
Equalization	Aerobic digester	Oxygen transfer equipt.
Neutralization	Vacuum filter	Trickling filter
Nutrient addition		
Sludge recycle pump		
Clarifier		
Diversion basin		
Polishing pond		

TABLE VIII-7

WASTEWATER TREATMENT COSTS FOR
BPT, NSPS and BAT Effluent Limitations
(ENR 2330 - May 1976 Costs)
Pharmaceutical Industry - Subcategory A

		Effluent		
	RWL	BPT	NSPS[2]	BAT[2]
Production 1.54×10^3 kg/day				
Production Days Per Year	365	365	365	365
Wastewater Flow - cu m/day	1162	1162	1162	1162
(gpd)	307,000	307,000	307,000	307,000
BOD Design Basis - % removal	---	90	91	97
- mg/1	4400	440	396	132
- kg/day	5113	511	460	153
COD Design Basis[3] - % removal	---	74	76	80
- mg/1	10,120	2631	2429	2024
TOTAL CAPITAL COSTS [1]		$ 4,260,700	$ 220,000	$ 710,100
Annual Costs				
Capital Recovery plus return at 10% @ 10 yrs.		694,500	35,900	115,700
Operating + Maintenance		589,500	29,100	85,500
Energy + Power		122,000	1,000	3,000
Total Annual Cost		$ 1,406,000	$ 66,000	$ 204,200

[1] From Table VIII-14
[2] Incremental cost over BPT cost
[3] Influent COD = 2.3 x influent BOD

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TABLE VIII-8

WASTEWATER TREATMENT COSTS FOR
BPT, NSPS and BAT Effluent Limitations
(ENR 2330 – May 1976 Costs)
Pharmaceutical Industry - Subcategory B

	RWL	Effluent BPT	Effluent NSPS[2]	Effluent BAT[2]
Production 0.236×10^3 kg/day				
Production Days Per Year [3]	260	260	260	260
Wastewater Flow - cu m/day	76	76	76	76
(gpd)	20,000	20,000	20,000	20,000
BOD Design Basis - % removal	---	90	93	93
- mg/l	225	23	16	16
- kg/day BOD	17	1.7	0.5	0.5
COD Design Basis - % removal	---	74	75	75
- mg/l	653	170	163	163
TOTAL CAPITAL COSTS [1]		$ 908,400	$ 56,000	$ 56,000
Annual Cost				
Capital Recovery plus return at 10% @ 10 yrs.		148,100	9100	9100
Operating + Maintenance		115,400	16,000	16,000
Energy + Power		2,000	200	200
Total Annual Costs		$ 265,500	$ 25,300	$ 25,300

[1] From Table VIII-15
[2] Incremental cost over BPT cost
[3] Treatment plant operates 365 days/yr
[4] Influent COD = 2.9 x Influent BOD

TABLE VIII-9

WASTEWATER TREATMENT COSTS FOR
BPT, NSPS and BAT Effluent Limitations
(ENR 2330 - May 1976 Costs)
Pharmaceutical Industry - Subcategory C

	RWL	Effluent BPT	Effluent NSPS[2]	Effluent BAT[2]
Production 18.75 x 10^3 kg/day				
Production Days Per Year	365	365	365	365
Wastewater Flow - cu m/day	3058	3058	3058	3058
(gpd)	808,000	808,000	808,000	808,000
BOD Design Basis - % removal	---	90	91	97
- mg/l	4560	456	410	137
- kg/day BOD	13,945	1395	1265	418
COD Design Basis[3] - % removal	---	74	76	80
- mg/l	10,488	2727	2519	2098
TOTAL CAPITAL COSTS [1]		\$ 8,137,300	\$ 380,000	\$ 1,272,600
Annual Costs				
Capital Recovery plus return at 10% @ 10 yrs.		1,326,400	62,000	207,400
Operating + Maintenance		945,700	42,000	113,300
Energy + Power		264,000	6,000	8,000
Total Annual Cost		\$ 2,536,100	\$ 110,000	\$ 328,700

[1] From Table VIII-16
[2] Incremental cost over BPT cost
[3] Influent COD = 2.3 x influent BOD

TABLE VIII -11

WASTEWATER TREATMENT COSTS FOR
BPT, NSPS and BAT Effluent Limitations
(ENR 2330 - May 1976 Costs)
Pharmaceutical Industry - Subcategory D

	RWL	Effluent BPT	NSPS[2]	BAT[2]
Production 8.8 x 10^3 kg/day				
Production Days Per Year[3]	260	260	260	260
Wastewater Flow - cu m/day	265	265	265	265
(gpd)	70,000	70,000	70,000	70,000
BOD Design Basis - % removal[5]	---	90	91	91
- mg/l	659	66	46	46
- kg/day	175	17.5	12.3	12.3
COD Design Basis[4] - % removal	---	74	75	75
- mg/l	1911	497	478	478
TOTAL CAPITAL COSTS [1]		$ 1,444,200	$ 98,000	$ 98,000
Annual Costs				
Capital Recovery plus return at 10% @ 10 yrs.		235,400	16,100	16,100
Operating + Maintenance		118,600	19,300	19,300
Energy + Power		15,000	300	300
Total Annual Cost		$ 369,000	$ 35,700	$ 35,700

1 - From Table VIII-17
2 - Incremental cost over BPT cost
3 - Treatment plant operates 365 days/year
4 - Influent COD - 2.9 x influent BOD
5 - Calculations show 90.9% BOD removal based on incremental removal with TSS

TABLE VIII-12

WASTEWATER TREATMENT COSTS FOR BPT, NSPS and BAT Effluent Limitations (ENR 2330 - May 1976 Costs) Pharmaceutical Industry - Subcategory E

	RWL	Effluent BPT	Effluent NSPS[2]	Effluent BAT[2]
Production Days Per Year [3]	260-365[4]	260	260	260
Wastewater Flow - cu m/day	114	114	114	114
(gpd)	30,000	30,000	30,000	30,000
BOD Design Basis - % removal	---	90	93	93
- mg/l	210	21	15	15
- kg/day	24	2.4	0.7	0.7
COD Design Basis - % removal	---	74	75	75
- mg/l	609	158	152	152
TOTAL CAPITAL COSTS [1]		$ 961,400	$ 58,000	$ 58,000
Annual Costs				
Capital Recovery plus return at 10% @ 10 yrs.		156,700	9500	9500
Operating + Maintenance		120,400	16,100	16,100
Energy + Power		3,600	300	300
Total Annual Cost		$ 281,200	$ 25,900	$ 25,900

[1] From Table VIII-18
[2] Incremental cost over BPT cost
[3] Treatment plant operates 365 days/yr
[4] 365 days/yr for large animals
[5] Influent COD = 2.9 x influent BOD

TABLE VIII-13

CAPITAL AND ANNUAL O&M COSTS PER UNIT OF WASTE FLOW FOR TYPICAL PHARMACEUTICAL INDUSTRY MODEL TREATMENT PLANTS

		BPT Model Plant Costs		NSPS Model Plant Costs (1)		BAT Model Plant Costs (1)	
Sub-category	Flow cu m/day (gpd)	Capital $/cu m/d ($/gpd)	Annual O&M(2) $/cu m/d ($/gpd)	Capital $/cu m/d ($/gpd)	Annual O&M(2) $/cu m/d ($/gpd)	Capital $/cu m/d ($/gpd)	Annual O&M(2) $/cu m/d ($/gpd)
A	1,162 (307,000)	3,667 (13.9)	612.3 (2.32)	189.3 (0.72)	25.90 (0.10)	611 (2.31)	76.16 (0.29)
B	75.7 (20,000)	12,000 (45.4)	1,551 (5.87)	739.8 (2.80)	214 (0.81)	(3)*	
C	3,058 808,000	2,661 (10.1)	395.6 (1.50)	124.3 (0.47)	15.7 (.06)	416.2 (1.58)	39.65 (0.15)
D	265 (70,000)	5,450 (20.6)	504.2 (1.91)	369.8 (4.9)	73.96 (0.28)	(3)*	
E	113.6 (30,000)	8,463 (32)	1091.5 (4.13)	510.6 (1.93)	144.36 (0.55)	(3)*	

(1) Incremental costs over BPT Model
(2) Annual O*M includes chemicals, labor, maintenance, taxes, insurance and energy (no capital recovery)
(3)* BAT limitations are met by NSPS treatment

The annual cost associated with hydraulically dependent unit processes is not a function of effluent level. On the other hand, the sizing of the organically dependent units should theoretically vary in direct proportion to the effluent level, e.g., reducing the BOD removal from 95 to 85 percent should reduce the sizes of the sludge handling equipment by approximately 10 percent. However, there are two complicating factors: 1) relatively few sizes of equipment are commercially available; and 2) capacity ranges are broad. These two factors, especially in regard to vacuum filters, tend to negate differentials in capital cost with decreasing treatment levels. In other words, the smallest equipment size commercially available is considerably oversized for the calculated load.

The relationship between design-varying contaminant levels and the design of aeration basins and oxygen transfer equipment is somewhat more complex. The levels are dependent on the hydraulic flow, organic concentration, sludge settleability and the relationship between mixing and oxygen requirements. For example, to reach a particular effluent level, a particular detention time at a given mixed-liquor concentration will be required. The oxygen transfer capacity of the aerators may or may not be sufficient to keep the mixed liquor suspended solids in suspension within the aeration basin. Therefore, required horsepower would be increased to fulfill a solids mixing requirement. On the other hand, the oxygen requirements may be such that the manufacturer's recommended aerator minimum spacing and water depth requirements would require that the basin volume be increased to accommodate oxygen transfer requirements.

Costs abstracted from Tables VIII-7 through VIII-12 are presented in Table VIII-13 on a per gallon basis. As expected, the estimated total capital and operation and maintenance costs for subcategory A and C are the highest in terms of dollars but the lowest in terms of a per gallon basis. This reflects the high wastewater flows that characterize these two subcategories. In addition, these wastewaters typically contain high concentrations of organic material, which require relatively long aeration times and more extensive sludge handling facilities.

The cost per gallon figures presented in Figure VIII-13 decrease with increasing flows, illustrating treatment system economies of scale.

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SUMMARY OF CAPITAL COSTS FOR BPT WASTEWATER TREATMENT
PHARMACEUTICAL INDUSTRY
(90% Removal)

Capital Cost (ENR 2330 May 1976 Costs) Subcategory A - 1162 cu m /day (.307 MGD)

Unit Processes Avg. Infl. BOD = 4400 mg/l
Avg. Infl. TSS = 3290 mg/l

Low Lift Pump Station 2 pumps-ea. 22 l/sec (350gpm)	$ 70,000	
Equalization Basin	---	
Equalization Basin Mixers	---	
Neutralization Tanks 2 - 8.3 cu m (2200 gal)	19,500	
Lime Addition Facilities .3 metric ton/day	101,000	
Sulphuric Acid Addition Facilities	---	
Primary Flocculator Clarifier 2 - 6.1 m (20 ft) dia.	128,000	
Sludge Pumps 3 units	14,400	
Aeration Basins 4 days 4655 cu m (1.23 mg)	240,000	
Aeration Basin Aerators 4 - 100 HP fixed	210,000	
Secondary Flocculator Clarifier 2 - 6.1 m (20 ft) dia	128,000	
Recycle Pumps 5 units	27,000	
Nutrient Addition Facilities	35,000	
Polymer Addition Facilities	16,000	
Sludge Thickener 10.7 m (39 ft) dia	90,000	
Aerobic Digester 2309 cu m (.61 MG)	185,000	
Digester Aerators 4 - 60 HP fixed	147,200	
Sludge Pumps 2 units	17,600	
Vacuum Filter 2 units ea. 18.4 sq. m (198 sq ft)	450,000	
Chlorination	34,500	
Flow Measurement & Sampling	24,000	
Control Building	188,500	
Diversion Basin 2323 cu m (0.61 mg)	20,000	
Polishing Pond 2 days	22,000	
Subtotal A (Unit Process Components in Place)		2,167,700
Piping 20% of A		
Electrical 14% of A		
Instrumentation 8% of A		
Sitework 6% of A		
Subtotal B (Miscellaneous Construction) 48% of A		1,040,496
Engineering 15% of A & B		
Contingencies 15% of A & B		
Subtotal C (Eng'g & Contingencies) 30% of A+B		962,458
Land 6 Acres @ $15,000		90,000
TOTAL SUBCATEGORY A (In place Constr. Cost) (90% BOD Removal)		$4,260,654

TABLE VIII - 15 12/6/76

SUMMARY OF CAPITAL COSTS FOR BPT WASTEWATER TREATMENT
PHARMACEUTICAL INDUSTRY
(90% BOD Removal)

Capital Cost (ENR 2330 May 1976 Costs) Subcategory B 75.7 cu m/day (.02 MGD)

Unit Processes
Avg. Infl. BOD = 225 mg/1
Avg. Infl. TSS = 80 mg/1

Low Lift Pump Station 2 - 6.3 1/sec (100 gpm)	$ 40,000	
Equalization Basin 151.4 cu m (40,000 gal)	38,000	
Equalization Basin Mixers 3 - 2 HP floating	14,500	
Neutralization Tanks	---	
Lime Addition Facilities	---	
Sulphuric Acid Addition Facilities	---	
Primary Flocculator Clarifier	---	
Sludge Pumps	---	
Aeration Basins 56.8 cu m (15,000 gal)	30,000	
Aeration Basin Aerators 2 - 2 HP floating	9,700	
Secondary Flocculator Clarifier 2 - 9.3 sq m (100 sq ft)	56,000	
Recycle Pumps 3 units	11,200	
Nutrient Addition Facilities	12,300	
Polymer Addition Facilities	16,000	
Sludge Thickener	---	
Aerobic Digester 23.3 cu m (6700 bal)	20,000	
Digester Aerators 2 - 2 HP	29,000	
Sludge Pumps 2 units	14,400	
Vacuum Filter	---	
Chlorination	24,300	
Flow Measurement & Sampling	21,800	
Control Building	124,800	
Diversion Basin	---	
Polishing Pond	---	
Subtotal A (Unit Process Components in Place)		462,000
Piping 20% of A		
Electrical 14% of A		
Instrumentation 8% of A		
Sitework 6% of A		
Subtotal B (Miscellaneous Construction) 48% of A		221,760
Engineering 15% of A & B		
Contingencies 15% of A & B		
Subtotal C (Eng'g & Contingencies) 30% of A+B		205,128
Land 1.3 Acres @ $15,000		19,500
TOTAL SUBCATEGORY B (In place Constr. Cost) (90% BOD Removal)		$ 908,388

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TABLE VIII-16

SUMMARY OF CAPITAL COSTS FOR BPT WASTEWATER TREATMENT
90% BOD Removal of which PHARMACEUTICAL INDUSTRY

Capital Cost (ENR 2330 May 1976 Costs) — Subcategory C 3058 cu m/day (.808 MGD)
Avge. Infl. BOD = 4560 mg/l
Avge. Infl. TSS = 447 mg/l

Unit Processes		
Low Lift Pump Station	$ 142,000	
Diversion Basin 6131 cu m (1.62 mg)	36,000	
Control Bldg.	325,000	
Neutralization Tanks 2 ea 17 cu m (4500 gal)	34,500	
Lime Addition Facilities (.82 met T) .9 TPD	142,000	
Sulphuric Acid Addition Facilities	24,000	
Primary Flocculator Clarifier 2 ea 9.1 m (30 ft)dia	260,000	
Sludge Pumps 3 units	14,400	
Aeration Basins 4 days 12,225 cu m (3.23 mg)	420,000	
Aeration Basin Aerators 10-100 HP	525,000	
Secondary Flocculator Clarifier 2 ea 9.1 m dia	260,000	
Recycle Pumps 3 units	14,400	
Nutrient Addition Facilities	70,000	
Polymer Addition Facilities	16,000	
Sludge Thickener 12.5 m (41 ft) dia	106,500	
Aerobic Digester 3520 cu m (.93 mg)	220,000	
Digester Aerators 8 50 HP fixed	256,000	
Sludge Pumps 2 units	11,200	
Vacuum Filter 2 units ea 20 sq m (316 sq ft)	600,000	
Chlorination	48,000	
Flow Measurement & Sampling	28,000	
Trickling Filter 23 m (75 ft) dia x 3.6 m	315,000	
Final Clarifier 2 ea - 9.1 m(30 ft) dia	260,000	
Polishing Pond 2 days	29,000	
Subtotal A (Unit Process Components in Place)		$ 4,167,000
Piping 20% of A		
Electrical 14% of A		
Instrumentation 8% of A		
Sitework 6% of A		
Subtotal B (Miscellaneous Construction) 48% of A		2,000,160
Engineering 15% of A & B		
Contingencies 15% of A & B		
Subtotal C (Eng'g & Contingencies) 30% of A+B		1,850,050
Land 8 Acres @ $15,000		120,000
TOTAL SUBCATEGORY C (In place Constr. Cost) (90% BOD Removal)		$ 8,137,310

TABLE VIII - 17

SUMMARY OF CAPITAL COSTS FOR BPT WASTEWATER TREATMENT
PHARMACEUTICAL INDUSTRY
(90% BOD Removal)

Capital Cost (ENR 2330 May 1976 Costs) Subcategory D 265 cu m/day (.07 MGD)
Avg. Infl. BOD = 659 mg/l
Unit Processes Avg. Infl. TSS = 106 mg/l

Low Lift Pump Station	2 - ea. 6.3 l/sec (100 gpm)	$ 40,000	
Equalization Basin	529.9 cu m	88,500	
Equalization Basin Aerators	3 - 2 HP floating	14,500	
Neutralization Tanks		---	
Lime Addition Facilities		---	
Sulphuric Acid Addition Facilities		---	
Primary Flocculator Clarifier		---	
Sludge Pumps		---	
Aeration Basins	280.1 cu m	80,000	
Aeration Basin Aerators	2 - 10 HP floating	15,400	
Secondary Flocculator Clarifier	2 - 9.3 sq m (100 sq ft)	56,000	
Recycle Pumps	3 units	11,200	
Nutrient Addition Facilities		18,800	
Polymer Addition Facilities		16,000	
Sludge Thickener		---	
Aerobic Digester	196.6 cu m (52,000 gal)	61,000	
Digester Aerators	4 - 5 HP floating	22,800	
Sludge Pumps	2 units	14,400	
Vacuum Filter	.75 sq m (8 sq ft)	100,000	
Chlorination		26,700	
Flow Measurement & Sampling		21,800	
Control Building		153,400	
Diversion Basin		---	
Polishing Pond		---	
Subtotal A (Unit Process Components in Place)			740,500
Piping	20% of A		
Electrical	14% of A		
Instrumentation	8% of A		
Sitework	6% of A		
Subtotal B (Miscellaneous Construction)	48% of A		355,440
Engineering	15% of A & B		
Contingencies	15% of A & B		
Subtotal C (Eng'g & Contingencies)	30% of A+B		328,782
Land 1.3	Acres @ $15,000		19,500
TOTAL SUBCATEGORY D (In place Constr. Cost) (90% BOD Removal)			$1,444,222

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SUMMARY OF CAPITAL COSTS FOR BPT WASTEWATER TREATMENT
PHARMACEUTICAL INDUSTRY
(90% BOD Removal)

Capital Cost (ENR 2330 May 1976 Costs) Subcategory E - 113.6 cu m (.03 MGD)
Avg. Infl. BOD = 310 mg/l
Unit Processes Avg. Infl. TSS = 132 mg/l

Low Lift Pump Station	2 - 6.3 l/sec (100 gpm)	$ 40,000	
Equalization Basin	215.7 cu m (.057 mg)	47,000	
Equalization Basin Mixers	3 - 2 HP floating	14,500	
Neutralization Tanks		---	
Lime Addition Facilities		---	
Sulphuric Acid Addition Facilities		---	
Primary Flocculator Clarifier		---	
Sludge Pumps		---	
Aeration Basins	109.7 cu m (.029 mg)	42,000	
Aeration Basin Aerators	2 - 2 HP	29,000	
Secondary Flocculator Clarifier	2 - 9.3 sq m (100 sq ft)	56,000	
Recycle Pumps	3 units	11,200	
Nutrient Addition Facilities		12,300	
Polymer Addition Facilities		16,000	
Sludge Thickener		---	
Aerobic Digester	47.3 cu m (12,500 gal)	26,000	
Digester Aerators	2 - 2 HP	9,600	
Sludge Pumps	2 units	14,400	
Vacuum Filter		---	
Chlorination		24,700	
Flow Measurement & Sampling		21,800	
Control Building		125,000	
Diversion Basin		---	
Polishing Pond		---	
Subtotal A (Unit Process Components in Place)			489,500
Piping	20% of A		
Electrical	14% of A		
Instrumentation	8% of A		
Sitework	6% of A		
Subtotal B (Miscellaneous Construction)	48% of A		235,000
Engineering	15% of A & B		
Contingencies	15% of A & B		
Subtotal C (Eng'g & Contingencies)	30% of A+B	217,400	217,400
Land 1.3	Acres @ $15,000		19,500
TOTAL SUBCATEGORY E (In place Constr. Cost) (90% BOD Removal)			$961,400

Energy

For the pharmaceutical manufacturing industry, the primary energy and power needs for BPT level treatment for all subcategories are pumps, aerators and vacuum filters. Under NSPS and BAT energy is needed for additional pumping equipment in all subcategories. The overall impact on energy for the industry is expected to be minimal. 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 subcagegories. A major use of treatment plant energy is for sludge incineration: 32% of the enrgy consumed by wastewater treatment plant operation was required for sludge incineration in one case: 78% in another case.

Tables VIII-7 through VIII-12 present the cost for energy and power for each treatment model for BPT, BAT and NSPS.

Sludge

Sludge cake quantities from vacuum filtration corresponding to each treatment system design are presented in Supplement A. The following table summarizes the sludge quantities generated by the model plants:

	Sludge Cake				Wet Sludge	
Subcat-egory	cu m/ yr	cu yd/ yr	kg/ day	lbs/ day	cu m/ day	gal/ day
A	11,176	14,783	3,447	7,592	--	--
B	--	--	--	--	0.64	168
C	17,035	22,533	5,255	11,575	--	--
D	240	317	74	163	--	--
E	--	--	--	--	0.94	312

Non-water Quality Aspects

The major non-water quality aspects of the proposed effluent limitations and guidelines are ultimate sludge disposal and noise and air pollution.

The BPT treatment model proposes sludge disposal by landfilling of the dewatered digested biological sludge for subcategories A, B, C, D and E 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 Solids Waste Information, U.S. EPA, Cincinnati, Ohio 45268.

Noise levels will not be appreciably affected with the implementation of the proposed treatment models. Most pharmaceutical plants generate relatively high noise levels and the pumps, aerators, mixers, etc. associated with end-of-pipe treatment plants will not add significantly to these noise levels.

Odor should not be a problem for an activated sludge plant if the plant is designed and operated properly. Covering of the aeration basin for odor control is practiced in some plants.

In addition to the cost information shown in this section the Economic Analysis Section of EPA will issue an economic document covering the economic and inflationary impact analysis of the pharmaceutical regulation published in the Federal Register on 11/17/76. Requests for this document should be directed to the Office of Planning and Evaluation, Environmental Protection Agency, Washington, D.C. 20460. This publication is issued to satisfy Executive Order 11821. 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 cost 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.

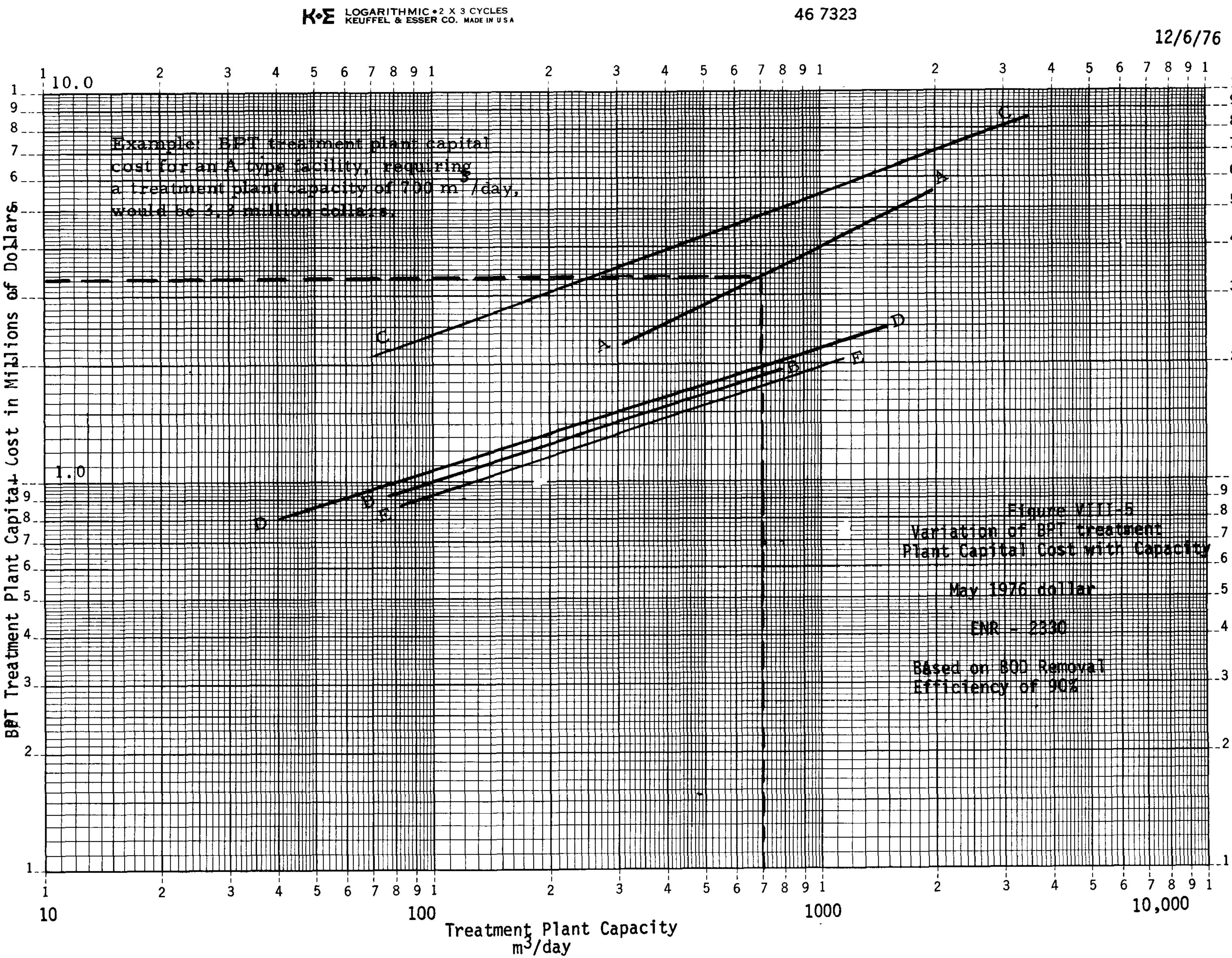

Figure VIII-5
Variation of BPT treatment Plant Capital Cost with Capacity

FIGURE VIII - 6
EQUALIZATION BASIN

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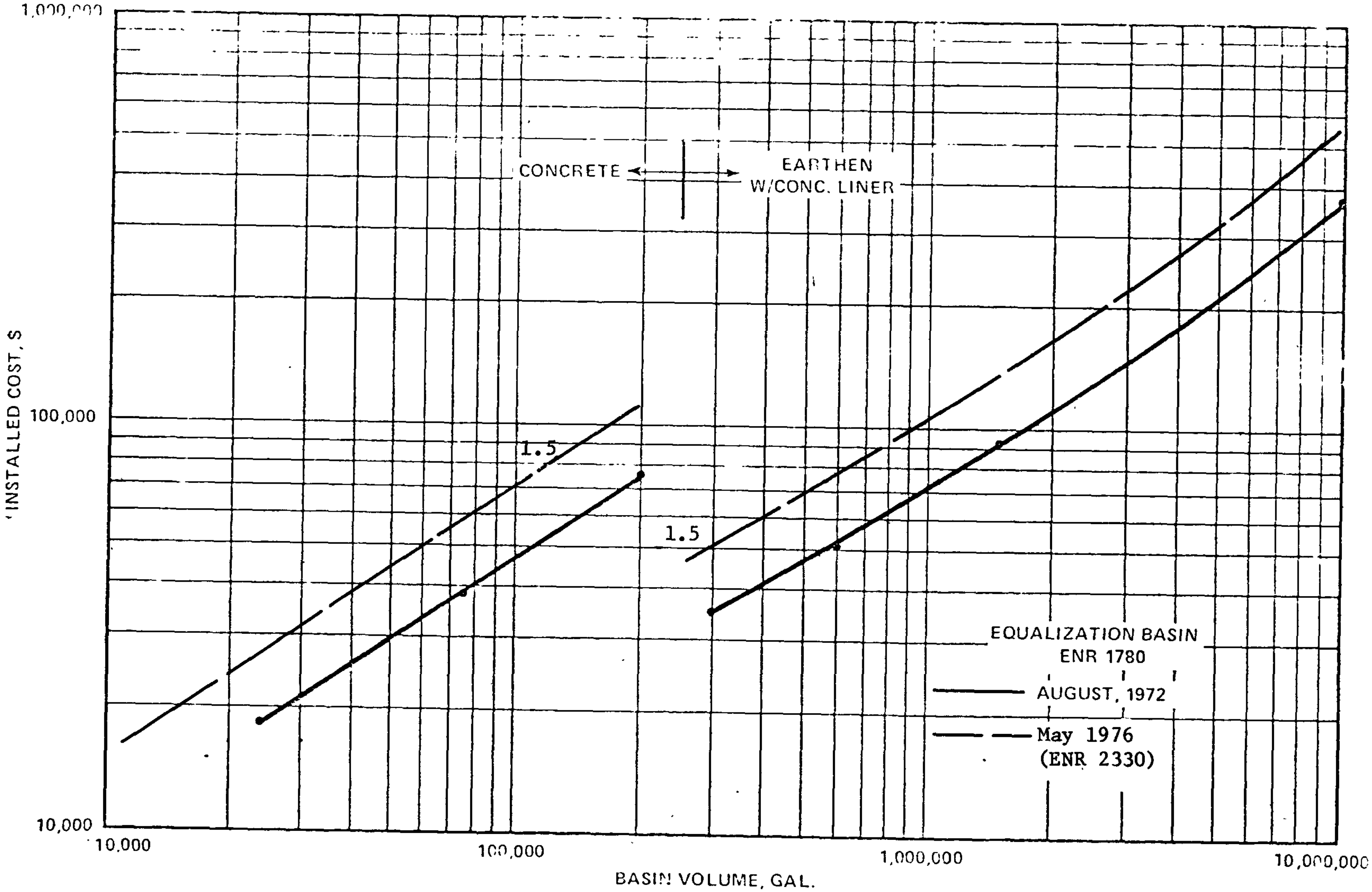

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FIGURE VIII - 7
PRIMARY AND SECONDARY CLARIFIER
INCLUDING MECHANISM

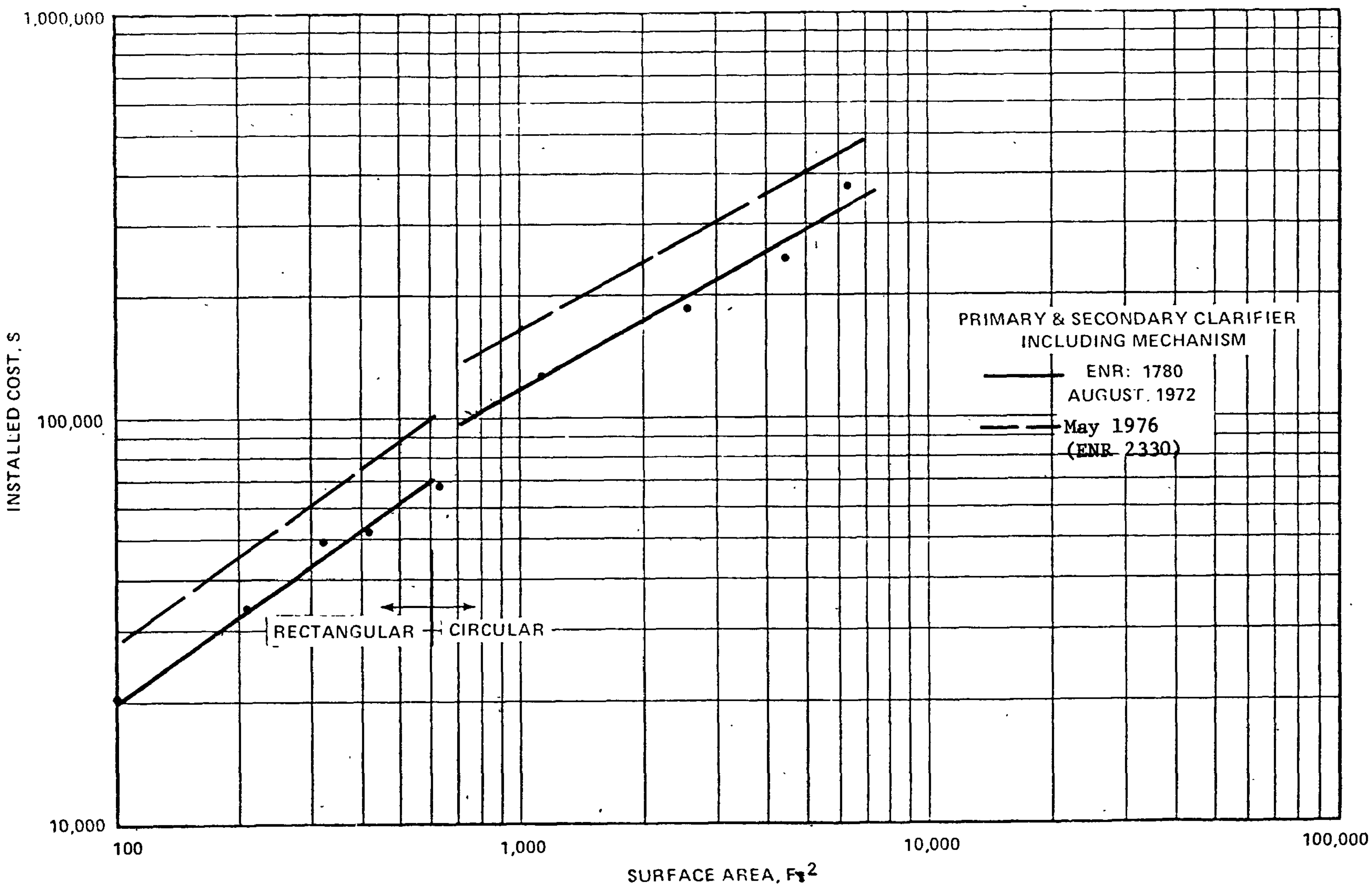

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FIGURE VIII - 8

NEUTRALIZATION TANKS INCLUDING MIXERS

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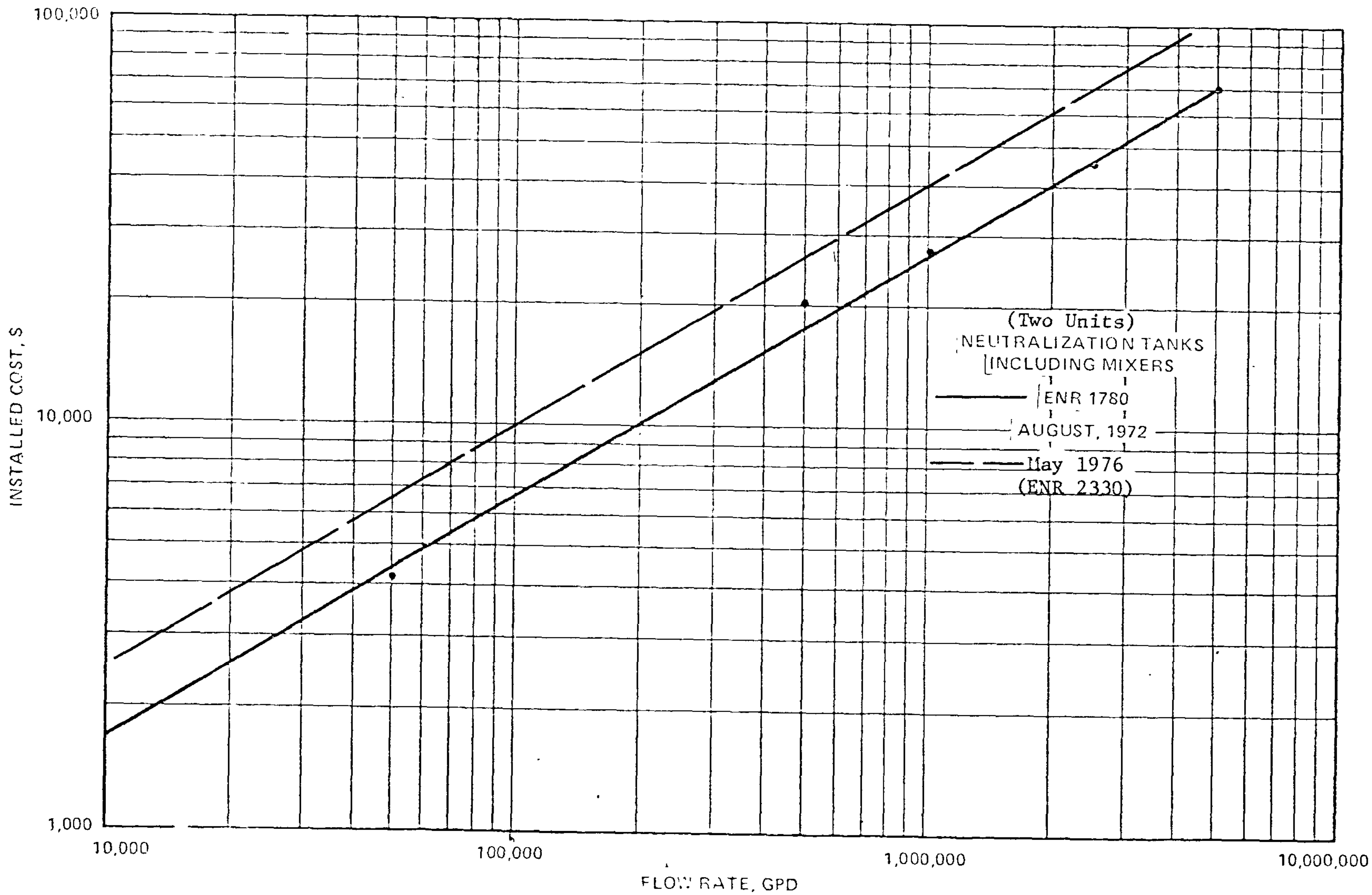

FIGURE VIII - 9
NEUTRALIZATION LIME CHEMICAL ADDITION FACILITIES INCLUDING STORAGE, FEEDING SLAKING, PUMPS, AND MIXERS.

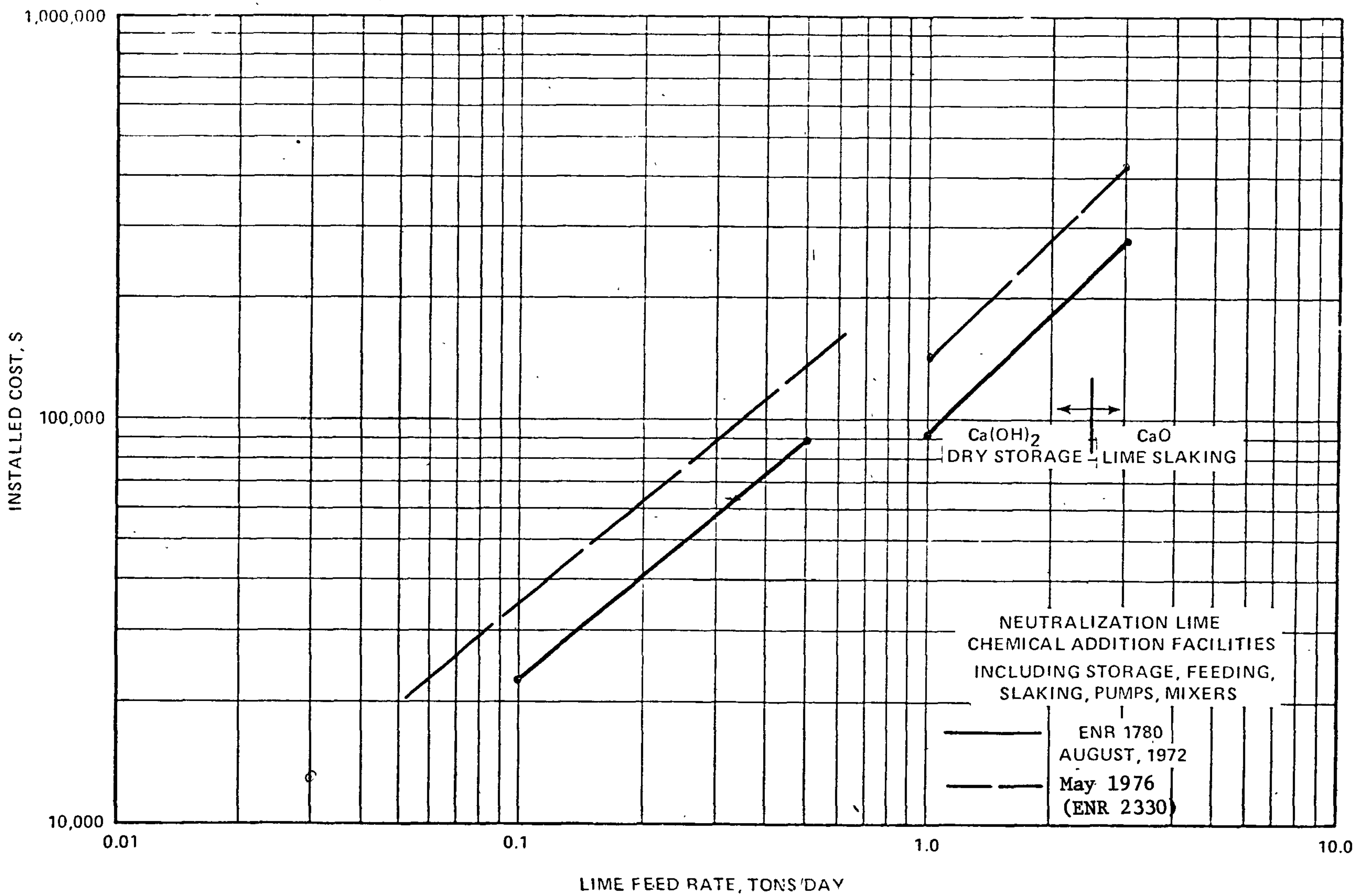

FIGURE VIII - 10
AERATION BASIN - CONCRETE BASINS

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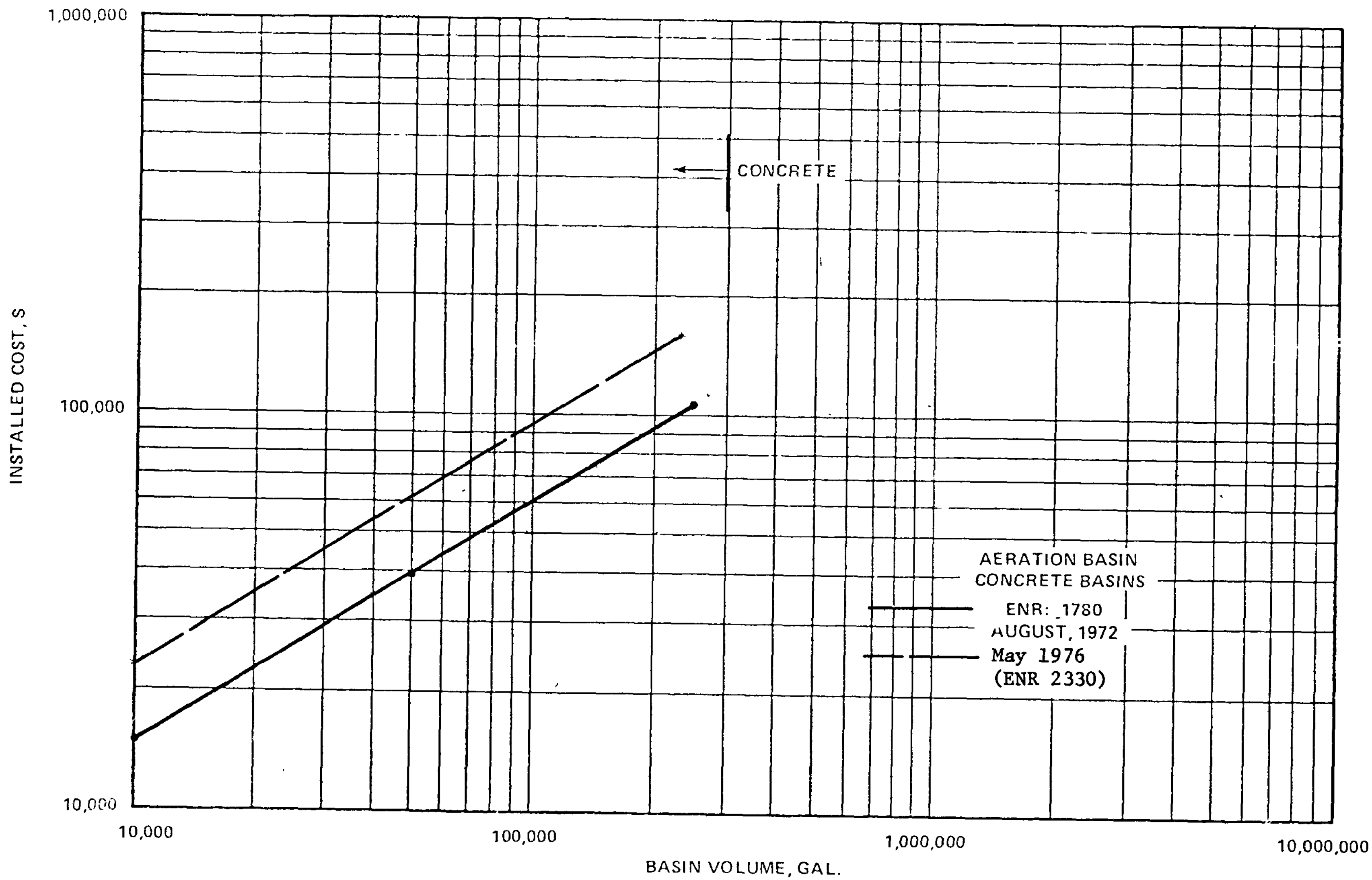

FIGURE VIII - 11
AERATION BASIN-EARTHEN w/CONC. LINER

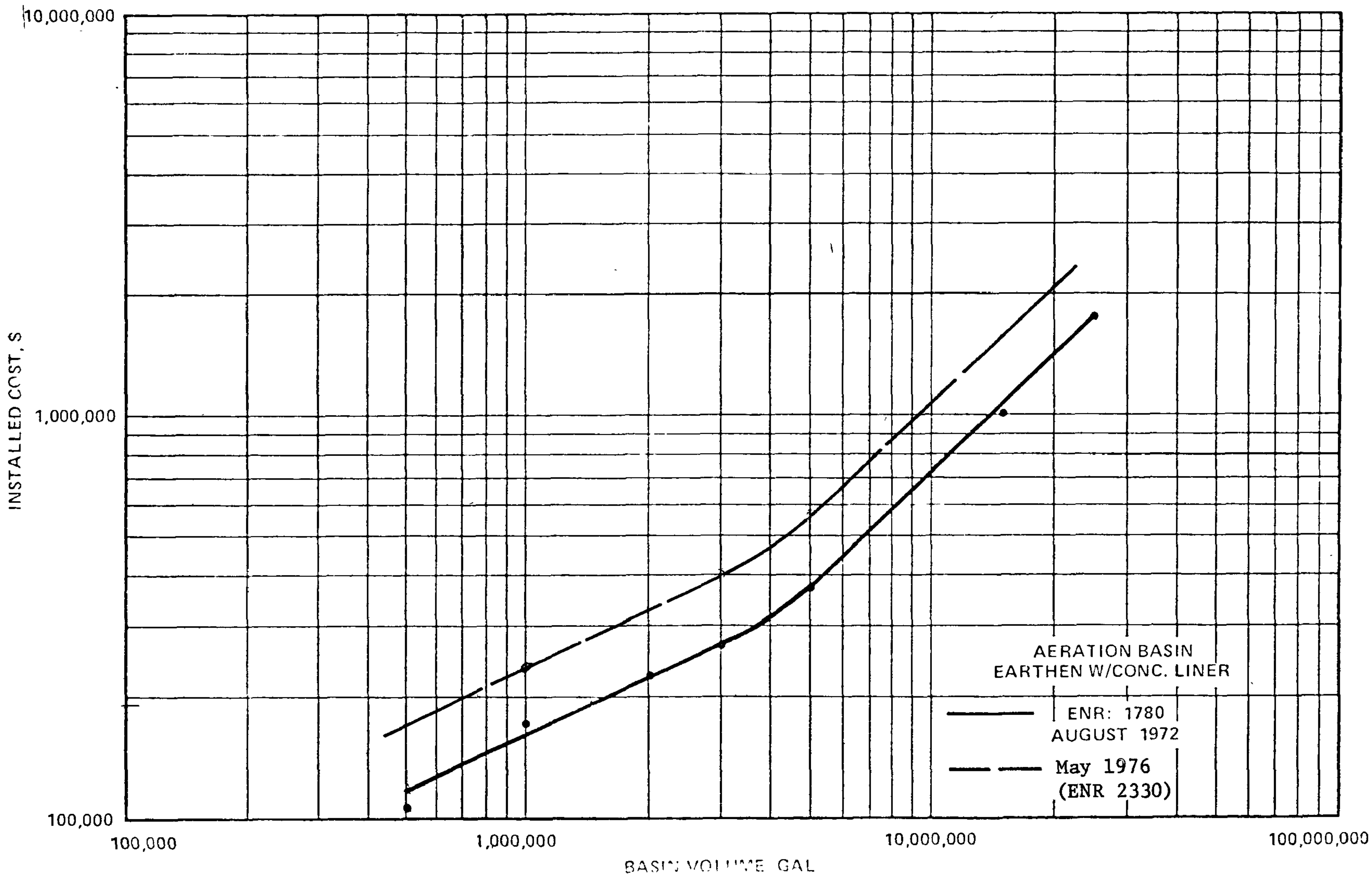

FIGURE VIII - 12
FIXED-MOUNTED AERATORS

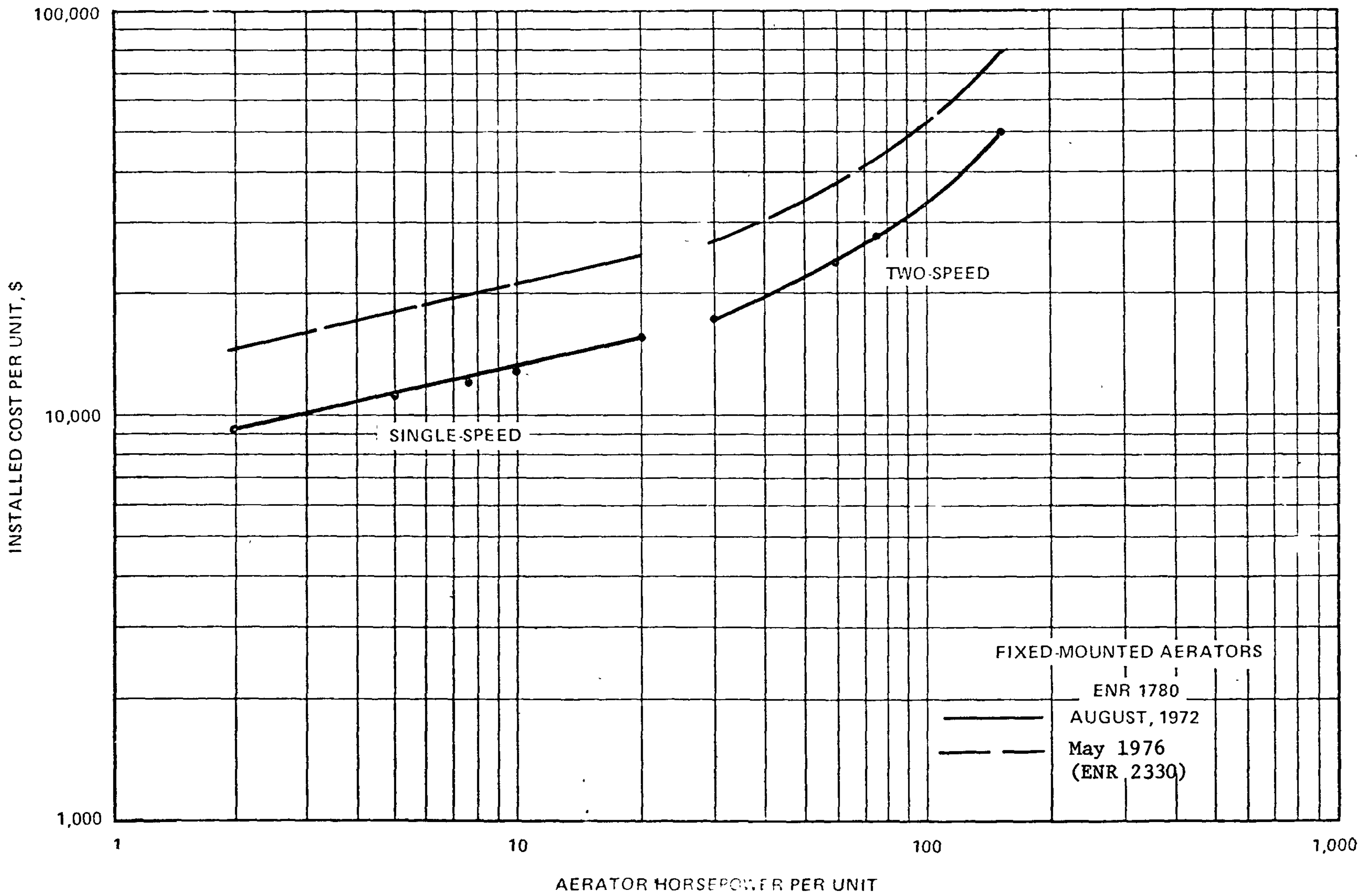

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FIGURE VIII - 13
FLOATING AERATORS

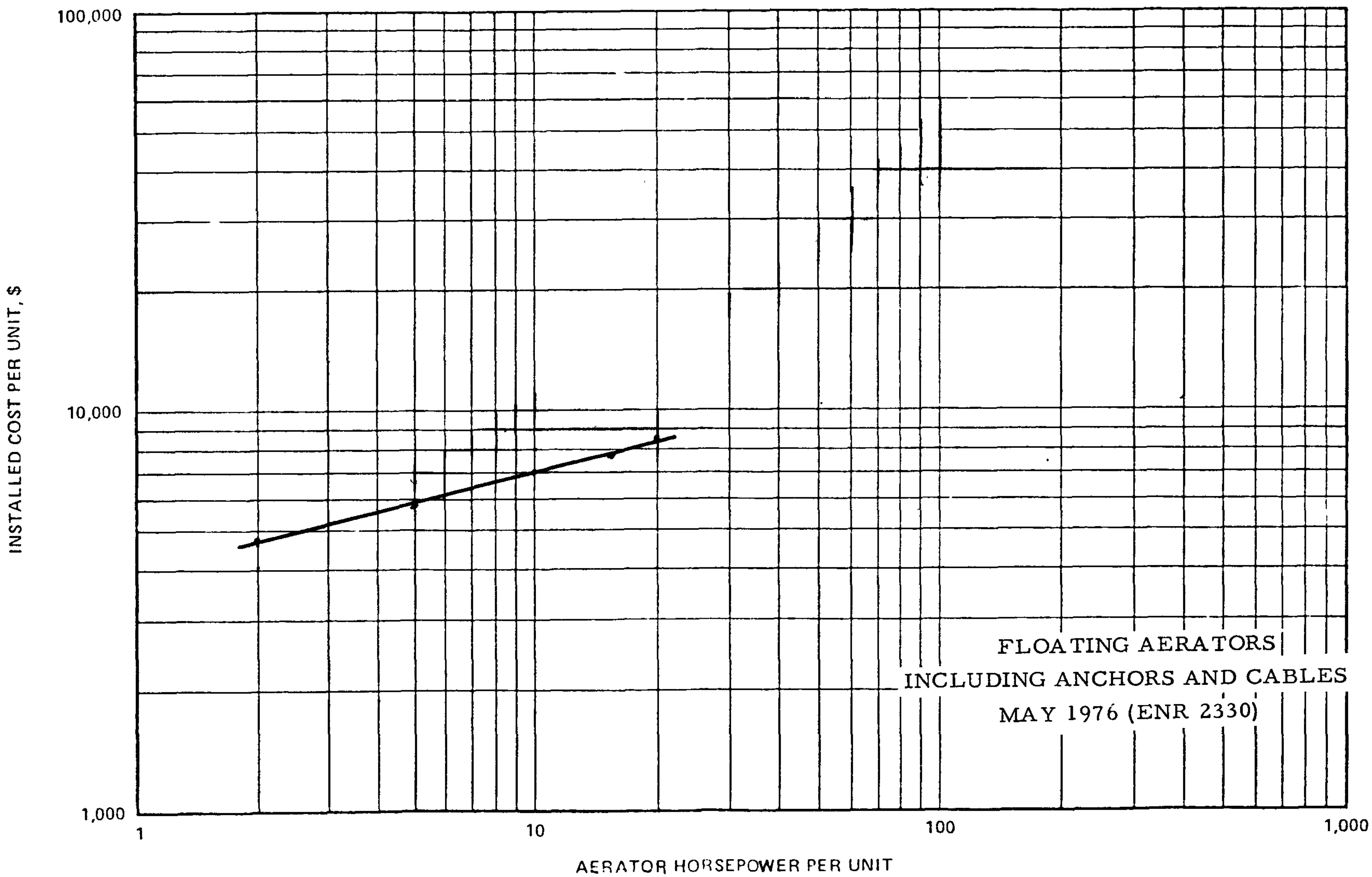

FIGURE VIII - 14
VACUUM FILTERS INCLUDING PUMPS, RECEIVERS, CONVEYOR & BUILDING

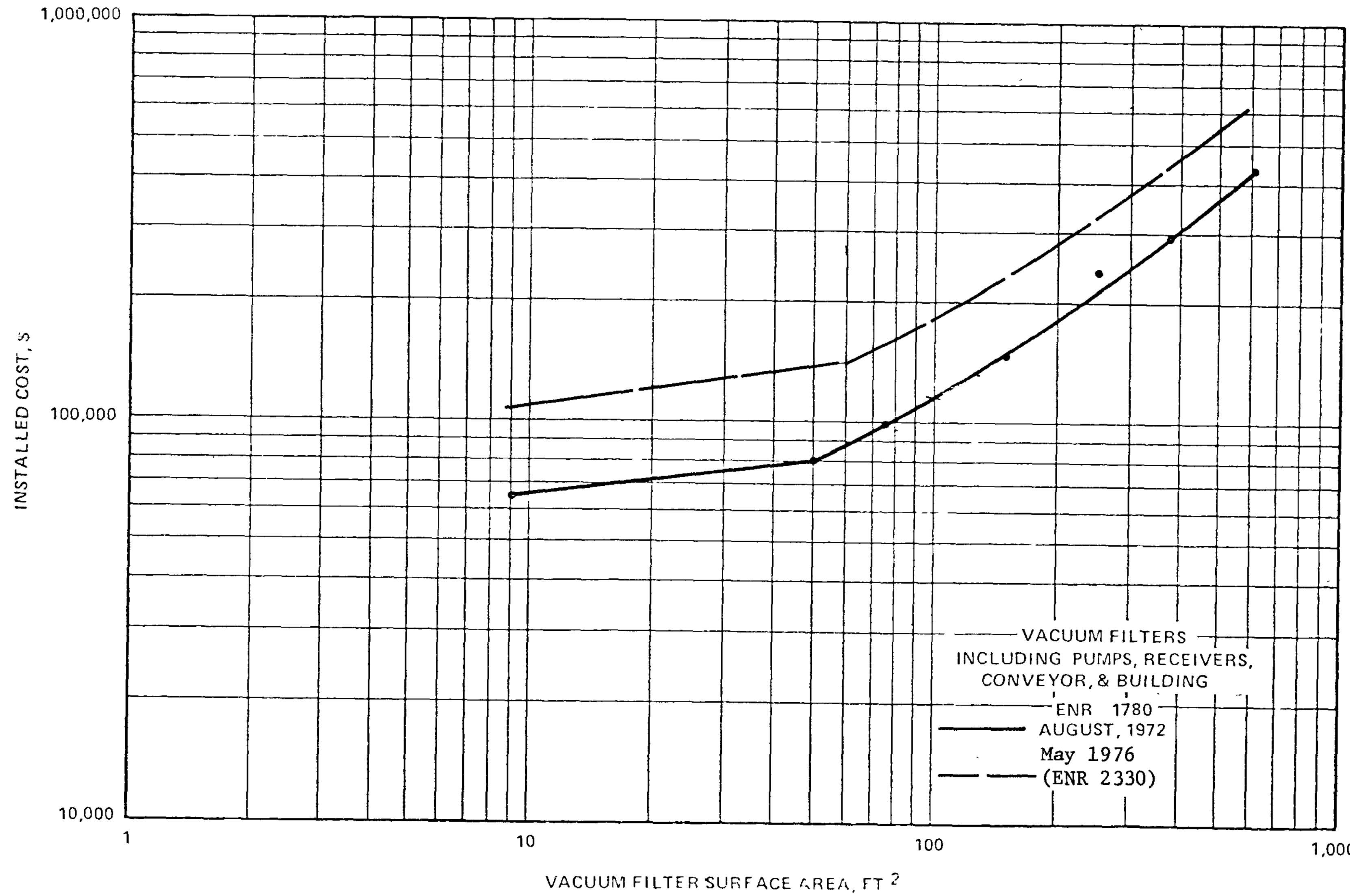

FIGURE VIII - 15
MULTI-MEDIA FILTERS INCLUDING FEED
WELL, PUMPS & SUMP

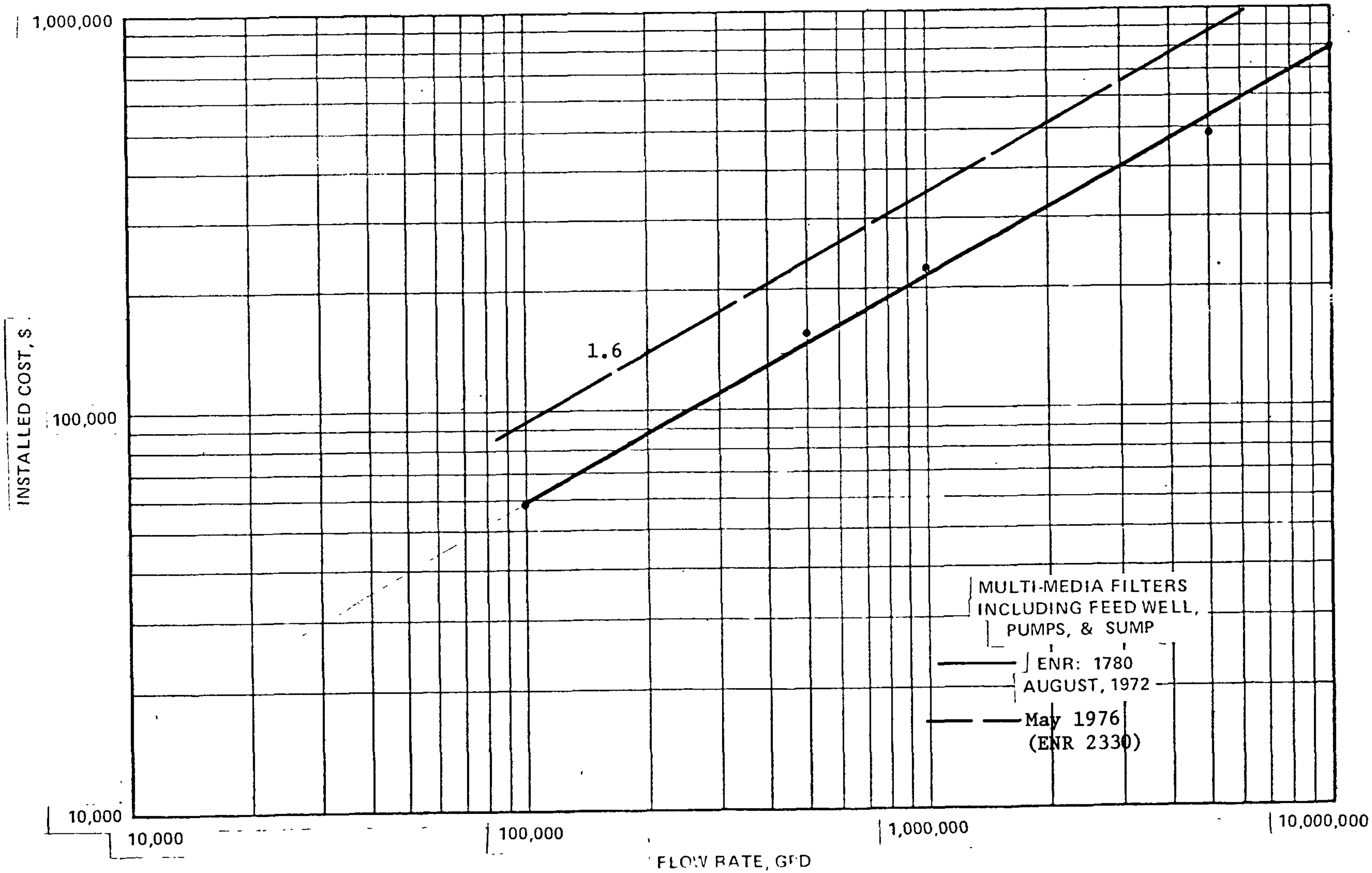

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FIGURE VIII - 16
CHLORINATION FACILITIES INCLUDING
CONTACT TANK, FEED, STORAGE, HANDLING

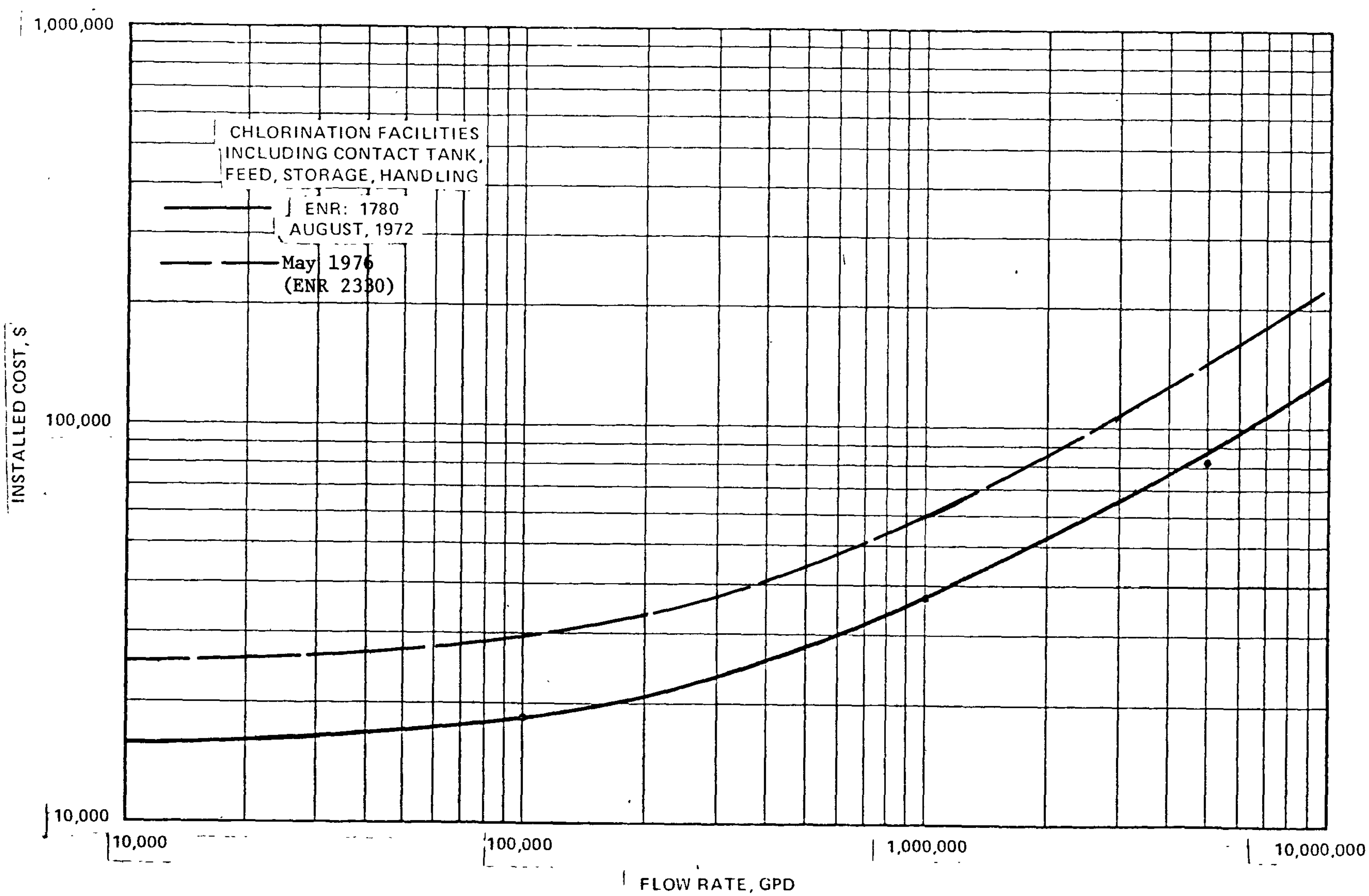
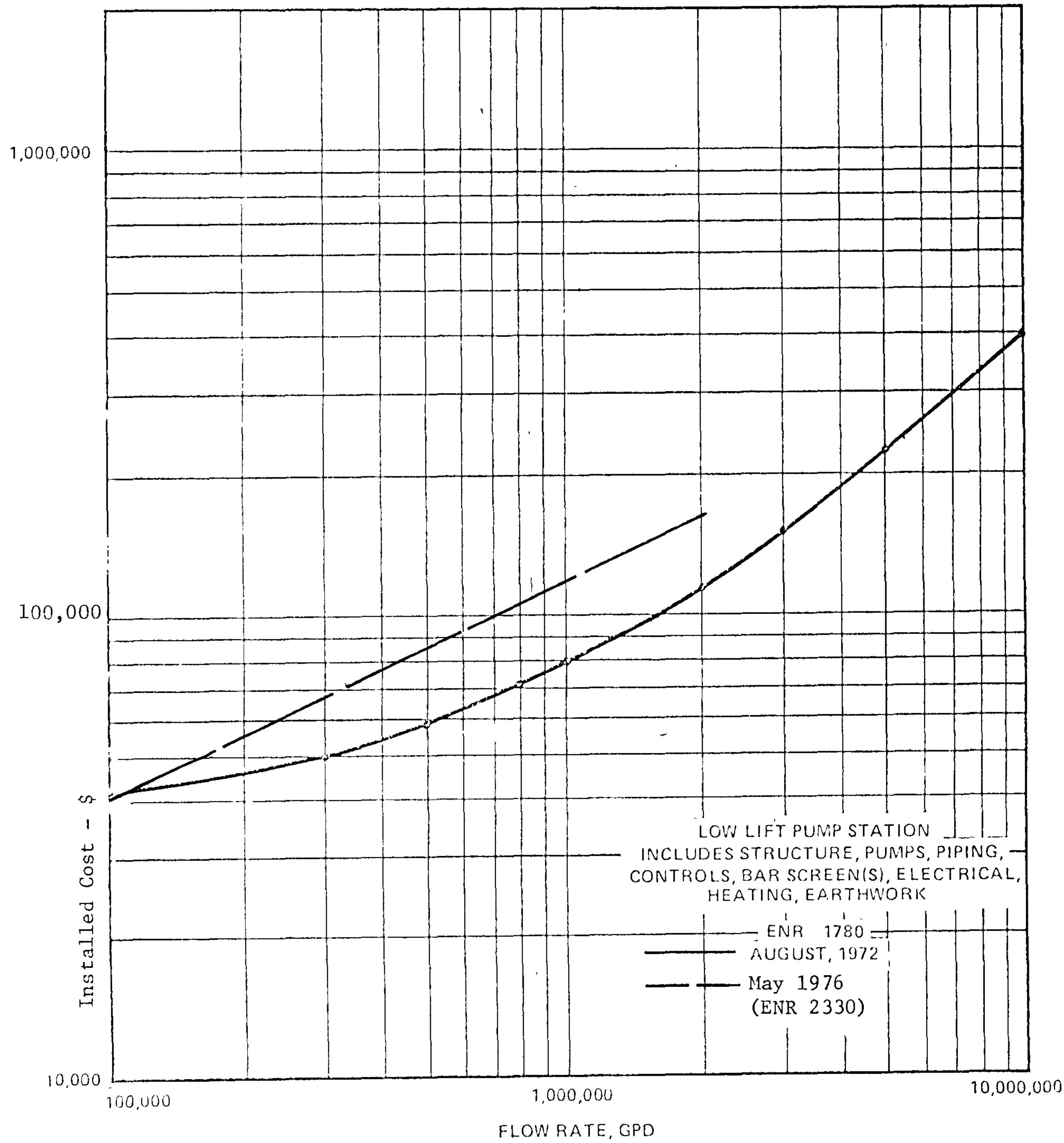


FIGURE VIII - 17
LOW LIFT PUMP STATION INCLUDES STRUCTURE, PUMPS, PIPING, CONTROLS, BAR SCREENS, ELECTRICAL, HEATING, AND EARTHWORK.



SECTION IX

BEST PRACTICABLE CONTROL TECHNOLOGY CURRENTLY AVAILABLE (BPT)

Pharmaceutical Manufacturing

Based on the information contained in Sections III through VIII of this report, effluent limitations and guidelines commensurate with the Best Practicable Control Technology Currently Available are presented in Table IX-1. The effluent limitations and guidelines specify required percent reduction of BOD_5 and COD, based on removals attainable through the application of BPT pollution control technology described in Section VII of this report. It should be emphasized that the removal efficiencies selected for determining BPT effluent limitations guidelines represent average historical values of exemplary waste treatment facilities within the pharmaceutical manufacturing point source category. For subcategories A and C, model BPT waste treatment technology includes equalization as part of the aeration facilities, neutralization, biological treatment, polishing pond and chlorination, with an empty diversion basin. In the subcategory C model a trickling filter and final clarification follow the usual secondary biological treatment. Sludge is digested, filtered and hauled to a landfill. For subcategories B, D and E the BPT model includes aerated equalization, biological treatment and final chlorination, with aerobic sludge digestion before disposal on land.

Historical data and observations during plant visits show wide variations in TSS reduction, particularly in subcategories A and C. Although polymer addition has been used successfully to reduce TSS in other industrial wastes, there is limited evidence to show that polymer addition will consistently yield predictable results with the highly variable types of subcategory A and C pharmaceutical wastes. The recommended limits in Table IX-1 are realistic values based on exemplary performance. However, it is not the intent of these effluent limitations and guidelines to specify either the unit wastewater flow which must be achieved, or the wastewater treatment practices which must be employed, at the individual pharmaceutical plants.

Because of the variations of RWL between and within subcategories (Section V) it was not possible to put the BPT effluent limitations on a per unit of production basis. These variations are caused in part because of the noncontinuous nature of many of the production processes, the different raw material/product ratios, the wide range in yields and the different technologies that are used to produce the same product. Therefore, the removal efficiencies identified in Section VII are to be applied to the waste loads entering the treatment facility.

In achieving the effluent limitations for the pharmaceutical manufacturing point source category, these concepts should be followed:

1. The pharmaceutical plant shall provide a wastewater treatment plant to reduce the concentrations of pollutants to the lowest possible level in the effluent.

2. The noted percentage removals of BOD_5 and COD and effluent TSS concentration shall be attained in the treatment plant. Percentage removals shall be calculated on the basis of monthly average kilograms per day of pollutant into and out of the plant. Removal of mycelia, evaporation of spent broth for disposal otherwise than to the wastewater system, stripping organic solvents out of waste streams, recovery or removal of any materials from the wastes, incineration of liquids able to support combustion, or the hauling away of part of the wastes shall not be considered as a part of the wastewater treatment system for the purposes of calculating the wastewater treatment plant efficiency.

3. Wastewater streams other than the main process streams and sanitary wastes, i.e. cooling waters, surface drainage, etc., shall be considered as separate discharges if they are not mixed with the process wastewater stream before its final discharge.

4. If different process streams and/or sanitary wastes are treated in different wastewater plants and the effluents are mixed before they discharge, the entire system shall be treated as one plant, but if the wastes discharge separately, then each plant must meet the performance requirements.

As indicated in Section VII, the following treatment efficiencies, based on historical treatment plant data were selected as being applicable for the determination of BPT effluent limitations and guidelines for all subcategories:

BOD5 - 94% removal efficiency

COD - 74% removal efficiency

The above BOD5 reduction (percent removal) could 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% 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.

As indicated in Section VII, the following TSS values were obtained from historical data:

Effluent TSS -- 274 mg/l for subcategories A & C
17.3 mg/l for subcategories B, D & E

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.

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. See Table IX which illustrates that the TSS for subcategories A and C drops from 274 mg/l to 178 mg/l when plant #2 is omitted form the exemplary composite calculation.

Table IX

Trial Calculation - Effluent TSS for Subcategory A and C
Exemplary Plants Without Plant #2

Plant	Subcategory	Eff. TSS mg/l
19	A C D	296
21	A C	147
22	A C	197
26	A B C D E	177
11	C	71
	Average =	178

The above TSS limitations for BPT were derived by using a similar logic path that was employed to generate the BOD_5 and COD removal efficiencies. Although the data shows high TSS values for subcategories A and C, it is believed that the TSS limitation could be reduced to 100 mg/l concentration where there is a significant content of chemical synthesis waste and fermentation wastes and to 20 mg/l where the influent is essentially free of chemical synthesis waste and fermentation waste.

When these BOD_5 and COD removal efficiencies are applied to influent BOD_5 and COD values of a specific plant the remainders are those values which are the proposed BPT effluent limitations, regardless of subcategory. The limitations are not to be exceeded by the average of 30 daily analyses of a specific effluent when sampled for 30 consecutive days.

Although the BPT regulation published in the Federal Register and supported by this document does not indicate the maximum day limitations for BOD_5, COD and TSS, it is expected that the permit writers will handle this issue on a case by case basis. Similarly, those known pollutants at a site specific location will be assigned appropriate effluent limitation values by the permit writer using 40 CFR 124 and 125. To assist the permit writer in arriving at reasonable maximum day limitations, daily variability factors and the ratio of daily variability factors to monthly variability factors are reported in Table XIII-3 in Section XIII.

TABLE IX-1a

BPT EFFLUENT LIMITATIONS AND GUIDELINES

Subcategory A - Fermentation Products Subcategory

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:

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% reduction in the long term daily average raw waste content of BOD5 multiplied by a variability factor of 3.0.

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% reduction in the long term daily average raw waste content of COD multiplied by a variability factor of 2.2.

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.

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 separable mycelia and solvents in those raw waste loads; provided that residual amounts of mycelia 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 separable 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.

The pH shall be within the range of 6.0 - 9.0 standard units.

TABLE IX - 1b

BPT EFFLUENT LIMITATIONS AND GUIDELINES

Subcategory B - Extraction Products Subcategory

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.

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

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

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.

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.

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

The pH shall be within the range of 6.0 - 9.0 standard units.

TABLE IX - 1c

BPT EFFLUENT LIMITATIONS AND GUIDELINES

Subcategory C - Chemical Synthesis Products Subcategory

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.

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

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

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.

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.

The pH shall be within the range of 6.0 - 9.0 standard units.

TABLE IX - 1d

BPT EFFLUENT LIMITATIONS AND GUIDELINES

Subcategory D - Mixing/Compounding and Formulation Subcategory

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.

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

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

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.

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.

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

The pH shall be within the range of 6.0 - 9.0 standard units.

TABLE IX - 1e

BPT EFFLUENT LIMITATIONS AND GUIDELINES

Subcategory E - Research Subcategory

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 research effort for a given pharmaceutical plant.

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

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

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.

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.

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

The pH shall be within the range of 6.0 - 9.0 standard units.

SECTION X

BEST AVAILABLE TECHNOLOGY ECONOMICALLY ACHIEVABLE (BAT)

Pharmaceutical Manufacturing

Effluent limitations and guidelines commensurate with the best available technology economically achievable are presented in Table X-1. BAT effluent limitations and guidelines were developed by evaluating those end-of-pipe modifications which seemed applicable for achieving better effluent quality. The BAT effluent limitations and guidelines presented in this section can be attained by adding various combinations of end-of-pipe technologies outlined in Section VII. In subcategory A, this consists of inserting a trickling filter, final clarifier and multi-media filter between the chlorination facilities and polishing pond of BPT treatment facilities. BAT effluent limitations and guidelines for subcategories B, D and E are based on the insertion of multi-media filters ahead of the chlorination facilities of BPT systems. To achieve BAT performance in subcategory C, a second stage trickling filter is inserted ahead of the BPT final clarifier and multi-media filters are inserted ahead of effluent chlorination.

BAT effluent limitations and guidelines were developed by the following procedures:

1. Although the BPT treatment models can produce reasonable levels of BOD_5 in the effluents of all subcategories it is recognized that control of COD and TSS is somewhat incidental to the reduction of BOD. Hence in BAT treatment the emphasis should be on improvement in COD and TSS removal.

2. To attack the more refractory substances such as solvent residues and organic acids, additional biological treatment by fixed film reactors is proposed. Trickling filtration and final clarification have already been included in the BPT system for subcategory C. Further biological treatment of subcategory A and subcategory C is necessary to achieve the proposed BAT limitations.

3. Wastewater Filtration Design Consideration, an EPA Technology Transfer Publication dated July 1974 and Process Design Manual for Upgrading Existing Wastewater Treatment Plants, an EPA Technology Transfer Publication dated

October, 1974, were reviewed. From these sources and from the contractor's experience in filtration of chemically treated potable water, it was concluded that multi-media pressure filters operating in parallel at an average filter rate of 3 gpm/sq ft for reasonable filtration cycles can reduce TSS by at least 75%.

4. Although a fixed film biological reactor and its associated clarifiers have been included in the BPT model for subcategory C, the needed TSS stabilization and further oxidation to reach BAT goals cannot be achieved through reduction of TSS alone. Therefore, the BAT system for the C model uses the factorial reduction of BOD and COD incidental to multi-media filtration and provides the remaining needed oxidation in a second stage trickling filter.

5. To express TSS limitations as concentrations, the percent removals were applied to BPT effluent concentrations found in reviewing the operating results of the exemplary plants in the subcategory B-D-E groups.

6. To determine maximum day limitations and maximum thirty day limitations for BOD_5, COD and TSS in each of the subcategories, variability factors are extracted from Table XIII-3. Note that the BPT monthly variability factors for BOD_5, COD and TSS published in the Federal Register, Vol. 41, No. 223 on Wednesday, November 17, 1976 are more lenient than the monthly variability factors reported in Table XIII-3. This difference occurred because the monthly variability factors reported in Table XIII-3 are from a larger data base than was used for the earlier monthly variability factor reported in the Federal Register.

TABLE X-1a

BAT EFFLUENT LIMITATIONS AND GUIDELINES

Subcategory 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 tne best practicable control technology currently available:

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 97% reduction in the long term daily average raw waste content of BOD5 multiplied by a variability factor of 3.0.

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 80% reduction in the long term daily average raw waste content of COD multiplied by a variability factor of 2.2.

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.

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 separable mycelia and solvents in those raw waste loads; provided that residual amounts of mycelia 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 separable 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.

The pH shall be within the range of 6.0 - 9.0 standard units.

TABLE X - 1b

BAT EFFLUENT LIMITATIONS AND GUIDELINES

SUBCATEGORY B

The allowable effluent discharge limitation for the daily average mass of BOD5 in any calendar month shall specifically reflect not less than 91% reduction in the long term daily average raw waste content of BOD5 multiplied by a variability factor of 3.0.

The allowable effluent discharge limitation for the daily average mass of COD in any calendar month shall specifically reflect not less than 75% reduction in the long term daily average raw waste content of COD multiplied by a variability factor of 2.2.

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.

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.

The average of daily TSS values for any calendar month shall not exceed 30 mg/l.

The pH shall be within the range of 6.0 - 9.0 standard units.

TABLE X - 1c
BAT EFFLUENT LIMITATIONS AND GUIDELINES
SUBCATEGORY C

The allowable effluent discharge limitation for the daily average mass of BOD5 in any calendar month shall specifically reflect not less than 97% reduction in the long term daily average raw waste content of BOD5 multiplied by a variability factor of 3.0.

The allowable effluent discharge limitation for the daily average mass of COD in any calendar month shall specifically reflect not less than 80% reduction in the long term daily average raw waste content of COD multiplied by a variability factor of 2.2.

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.

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.

The pH shall be within the range of 6.0 - 9.0 standard units.

TABLE X - 1d
BAT EFFLUENT LIMITATIONS AND GUIDELINES
SUBCATEGORY D

The allowable effluent discharge limitation for the daily average mass of BOD5 in any calendar month shall specifically reflect not less than 91% reduction in the long term daily average raw waste content of BOD5 multiplied by a variability factor of 3.0.

The allowable effluent discharge limitation for the daily average mass of COD in any calendar month shall specifically reflect not less than 75% reduction in the long term daily average raw waste content of COD multiplied by a variability factor of 2.2.

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.

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.

The average of daily TSS values for any calendar month shall not exceed 30 mg/l.

The pH shall be within the range of 6.0 - 9.0 standard units.

TABLE X - 1e

BAT EFFLUENT LIMITATIONS AND GUIDELINES
SUBCATEGORY E

The allowable effluent discharge limitation for the daily average mass of BOD5 in any calendar month shall specifically reflect not less than 91% reduction in the long term daily average raw waste content of BOD5 multiplied by a variability factor of 3.0.

The allowable effluent discharge limitation for the daily average mass of COD in any calendar month shall specifically reflect not less than 75% reduction in the long term daily average raw waste content of COD multiplied by a variability factor of 2.2.

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.

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.

The average of daily TSS values for any calendar month shall not exceed 30 mg/l.

The pH shall be within the range of 6.0 - 9.0 standard units.

SECTION XI

NEW SOURCE PERFORMANCE STANDARDS (NSPS)

General

The term "new source" is defined in the "Federal Water Pollution Control Act Amendments of 1972" to mean "any source, the construction of which is commenced after the publication of proposed regulations prescribing a standard of performance". Technology applicable to new sources shall be the Best Available Demonstrated Control Technology (NSPS), defined by a determination of what higher levels of pollution control can be attained through the use of improved production process and/or wastewater treatment techniques. Thus, in addition to considering the best in-plant and end-of-pipe control technology, NSPS technology is to be based upon an analysis of how the level of effluent may be reduced by changing the production process itself.

Pharmaceutical Manufacturing

New source performance standards commensurate with NSPS for the pharmaceutical manufacturing point source category are presented in Table XI-1. These performance standards are attainable with the end-of-pipe treatment technology outlined in Section VII, which consists of the addition of filtration to the treatment system proposed as BPT technology for subcategories A, B, C, D and E.

For subcategories B, D and E, new source performance standards are identical to BAT effluent limitations and guidelines. For subcategory A, the new source performance standards are based upon addition of multi-media filtration to the proposed BPT systems, without the tertiary oxidation-clarification steps proposed to meet BAT limitations. The rationale for determining NSPS limitations is the same as that applied to BAT treatment in Section X, except that the tertiary biological oxidation step is omitted. For subcategory C, new soruce performance standards are based on multi-media filters following the polishing pond which provides filter influent storage plus BPT unit operations. Although specific processes have been mentioned in connection with estimates of costs for model plants, the use of other equivalent processes is not precluded.

Applicable daily and monthly variability factors for BOD_5, COD and TSS can be extracted from Table XIII-3 in Section XIII.

TABLE XI-1a

NSPS EFFLUENT LIMITATIONS AND GUIDELINES

Subcategory 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:

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 91% reduction in the long term daily average raw waste content of BOD5 multiplied by a variability factor of 3.0.

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 76% reduction in the long term daily average raw waste content of COD multiplied by a variability factor of 2.2.

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.

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 separable mycelia and solvents in those raw waste loads; provided that residual amounts of mycelia 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 separable 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.

The pH shall be within the range of 6.0 - 9.0 standard units.

TABLE XI -1b
NSPS EFFLUENT LIMITATIONS AND GUIDELINES
SUBCATEGORY B

The allowable effluent discharge limitation for the daily average mass of BOD5 in any calendar month shall specifically reflect not less than 91% reduction in the long term daily average raw waste content of BOD5 multiplied by a variability factor of 3.0.

The allowable effluent discharge limitation for the daily average mass of COD in any calendar month shall specifically reflect not less than 75% reduction in the long term daily average raw waste content of COD multiplied by a variability factor of 2.2.

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.

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.

The average of daily TSS values for any calendar month shall not exceed 30 mg/l.

The pH shall be within the range of 6.0 - 9.0 standard units.

TABLE XI - 1c
NSPS EFFLUENT LIMITATIONS AND GUIDELINES
SUBCATEGORY C

The allowable effluent discharge limitation for the daily average mass of BOD5 in any calendar month shall specifically reflect not less than 91% reduction in the long term daily average raw waste content of BOD5 multiplied by a variability factor of 3.0.

The allowable effluent discharge limitation for the daily average mass of COD in any calendar month shall specifically reflect not less than 76% reduction in the long term daily average raw waste content of COD multiplied by a variability factor of 2.2.

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.

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.

The pH shall be within the range of 6.0 - 9.0 standard units.

TABLE XI - 1d
NSPS EFFLUENT LIMITATIONS AND GUIDELINES
SUBCATEGORY D

The allowable effluent discharge limitation for the daily average mass of BOD5 in any calendar month shall specifically reflect not less than 91% reduction in the long term daily average raw waste content of BOD5 multiplied by a variability factor of 3.0.

The allowable effluent discharge limitation for the daily average mass of COD in any calendar month shall specifically reflect not less than 75% reduction in the long term daily average raw waste content of COD multiplied by a variability factor of 2.2.

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.

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.

The average of daily TSS values for any calendar month shall not exceed 30 mg/l.

The pH shall be within the range of 6.0 - 9.0 standard units.

TABLE XI - 1e
NSPS EFFLUENT LIMITATIONS AND GUIDELINES
SUBCATEGORY E

The allowable effluent discharge limitation for the daily average mass of BOD5 in any calendar month shall specifically reflect not less than 91% reduction in the long term daily average raw waste content of BOD5 multiplied by a variability factor of 3.0.

The allowable effluent discharge limitation for the daily average mass of COD in any calendar month shall specifically reflect not less than 75% reduction in the long term daily average raw waste content of COD multiplied by a variability factor of 2.2.

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.

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.

The average of daily TSS values for any calendar month shall not exceed 30 mg/l.

The pH shall be within the range of 6.0 - 9.0 standard units.

SECTION XII

PRETREATMENT STANDARDS

General

Pollutants from specific processes within the pharmaceutical manufacturing industry may interfere with, pass through, or otherwise be incompatible with publicly owned treatment works (municipal system). The following sections examine the general wastewater characteristics of the various industries and the pretreatment unit operations which may be applicable to the pharmaceutical manufacturing point source category.

Pharmaceutical Manufacturing

The majority of the manufacturing plants in the pharmaceutical manufacturing point source category discharge their wastewaters into municipal sewage collection systems. The major sources of wastewaters in the pharmaceutical industry are product washings, extraction and concentration procedures and equipment washdown. Wastewaters generated by this industry have high concentrations of BOD5, COD, TSS and volatile organics. Wastewaters from some chemical synthesis and fermentation operations may contain metals (Cu, Ni, Hg, etc.) or cyanide and have anti-bacterial constituents, which may exert a toxic effect on biological waste treatment processes. For example, one class of pharmaceutical chemicals produced is bacteriostats, disinfectants and compounds used for sterilizing public facilities, hospitals, etc. Since these products are, by nature, disinfectants, a biological treatment system could be deactivated if the raw effluent from such a manufacturing process was directly charged to the treatment system at too high a concentration. Hence, it may be necessary to equalize or chemically treat process effluents. This pretreated effluent, in certain circumstances, should then be acceptable for treatment in a conventional municipal system.

Considerations significant to the design of a pretreatment plant which will receive pharmaceutical plant effluent are the highly variable BOD5 loadings, high chlorine demand, presence of surface-active agents and the lack of required nutrients which may characterize the wastewater.

In view of the wastewater characteristics discussed above, it was concluded that certain production techniques could be grouped together on the basis of pollutants requiring

Table XII -1

Pretreatment Unit Operations

Pharmaceutical Industry

Pretreatment Sub-Group	Suspended Biological System	Fixed Biological System	Independent Physical Chemical System
1	Chemical Precipitation (Metals) + Solvent Separation + Equalization + Neutralization + Cyanide Oxidation + Spill Protection	Chemical Precipitation (Metals) + Solvent Separation + Equalization + Neutralization + Cyanide Oxidation + Spill Protection	Chemical Precipitation (Metals) + Solvent Separation + Equalization + Neutralization + Cyanide Oxidation + Spill Protection
2	Equalization + Neutralization	Equalization + Neutralization	Equalization + Neutralization

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pretreatment. Accordingly, the previously determined five technology subcategories for the pharmaceutical industry were divided into two pretreatment sub-groups as follows:

Sub-group 1	Sub-group 2
Subcategory A	Subcategory B
Subcategory C	Subcategory D
	Subcategory E

The principal difference in the general characteristics of the process wastewaters generated by the process techniques in these two sub-groups is that the wastewaters of Sub-group 1 are more likely to include significant amounts of metals, cyanide and spent solvents. The wastewaters generated by the two process subcategories in Sub-group 1 are also generally much higher strength wastes than those from the Sub-group 2 process subcategories.

The types and amounts of metals and spent solvents in the wastewater from a pharmaceutical manufacturing process depend primarily on the manufacturing process and on the amounts and types of catalysts and solvents lost from the process. Most catalysts and solvents are expensive and therefore are recovered for reuse. Only unrecoverable catalysts (metals), generally in small concentrations and spent solvents appear in the wastewater.

Point sources in the pharmaceutical industries generate wastewaters on an intermittent basis and equalization may be needed as a pretreatment step. When solvents are used for extraction, solvent removal can be accomplished by using gravity separation and skimming. Neutralization may be required to neutralize acidic or alkaline wastewaters generated from the production of specific pharmaceutical products. The metals present in some pharamceutical wastes are in many cases so low in concentration that the removal of metals is not required from the standpoint of treatability characteristics. However, the effluent limitations for metals and toxic pollutants may require additional pretreatment (chemical precipitation) for removal of these materials from wastewaters discharged to POTWs.

The pretreatment unit operations which may be necessary for various types of joint treatment facilities are shown in Table XII-1. The pretreatment unit operations which may be required for Sub-group 1 consist of equalization, neutralization, solvent separation, cyanide removal and spill protection for chemical storage areas. For Sub-group 2 the general requirements are equalization and neutralization. In both subgroups, if the oxygen demands or holding conditions are such as to cause oxygen depletion, aeration may be necessary to control odors and hydrogen sulfide.

In the near future, it is anticipated that a survey of the pharmaceutical manufacturing point sources will be conducted to determine whether or not the priority pollutants listed in Table XII-2 are present in measurable quantities in the effluents from these plants. In addition, it is contemplated that various levels of treatment and the related cost for treatment will be investigated.

Table XII-2

Recommended List of Priority Pollutants

Compound Name

1. *acenaphthene
2. *acrolein
3. *acrylonitrile
4. *benzene
5. *benzidine
6. *carbon tetrachloride (tetrachloromethane)

*Chlorinated benzenes (other than dichlorobenzenes)

7. chlorobenzene
8. 1,2,4-trichlorobenzene
9. hexachlorobenzene

*Chlorinated ethanes (including 1,2-dichloroethane, 1,1,1-trichloroethane and hexachloroethane)

10. 1,2-dichloroethane
11. 1,1,1-trichloroethane
12. hexachloroethane
13. 1,1-dichloroethane
14. 1,1,2-trichloroethane
15. 1,1,2,2-tetrachloroethane
16. chloroethane

*Chloroalkyl ethers (chloromethyl, chloroethyl and mixed ethers)

17. bis(chloromethyl) ether
18. bis(2-chloroethyl) ether
19. 2-chloroethyl vinyl ether (mixed)

*<u>Chlorinated naphthalene</u>

20. 2-chloronaphthalene

*<u>Chlorinated phenols</u> (other than those listed elsewhere; includes trichlorophenols and chlorinated cresols)

21. 2,4,6-trichlorophenol
22. parachlorometa cresol
23. *chloroform (trichloromethane)
24. *2-chlorophenol

*<u>Dichlorobenzenes</u>

25. 1,2-dichlorobenzene
26. 1,3-dichlorobenzene
27. 1,4-dichlorobenzene

*<u>Dichlorobenzidine</u>

28. 3,3'-dichlorobenzidine

*<u>Dichloroethylenes</u> (1,1-dichloroethylene and 1,2-dichloroethylene)

29. 1,1-dichloroethylene
30. 1,2-<u>trans</u>-dichloroethylene
31. *2,4-dichlorophenol

*<u>Dichloropropane and dichloropropene</u>

32. 1,2-dichloropropane
33. 1,3-dichloropropylene (1,3-dichloropropene)
34. *2,4-dimethylphenol

*<u>Dinitrotoluene</u>

35. 2,4-dinitrotoluene
36. 2,6-dinitrotoluene
37. *1,2-diphenylhydrazine
38. *ethylbenzene
39. *fluroanthene

*<u>Haloethers</u> (other than those listed elsewhere)

40. 4-chlorophenyl phenyl ether
41. 4-bromophenyl phenyl ether
42. bis(2-chloroisopropyl) ether
43. bis(2-chloroethoxy) methane

*Halomethanes (other than those listed elsewhere)

44. methylene chloride (dichlorcmethane)
45. methyl chloride (chloromethane)
46. methyl bromide (bromomethane)
47. bromoform (tribromomethane)
48. dichlorobromomethane
49. trichlorofluoromethane
50. dichlorodifluoromethane
51. chlorodibromomethane
52. *hexachlorobutadiene
53. *hexachlorocyclopentadiene
54. *isophorone
55. *naphthalene
56. *nitrobenzene

*Nitrophenols (including 2,4-dinitrophenol and dinitrocresol)

57. 2-nitrophenol
58. 4-nitrophenol
59. *2,4-dinitrophenol
60. 4,6-dinitro-o-cresol

*Nitrosamines

61. N-nitrosodimethylamine
62. N-nitrosodiphenylamine
63. N-nitrosodi-n-propylamine
64. *pentachlorophenol
65. *phenol

*Phthalate esters

66. bis(2-ethylhexyl) phthalate
67. butyl benzyl phthalate
68. di-n-butyl phthalate
69. diethyl phthalate
70. dimethyl phthalate

*Polynuclear aromatic hydrocarbons

71. 1,2-benzanthracene
72. benzo (a)pyrene (3,4-benzopyrene)

73. 3,4-benzofluoranthene
74. 11,12-benzofluoranthene
75. chrysene
76. acenaphthylene
77. anthracene
78. 1,12-benzoperylene
79. fluroene
80. phenanthrene
81. 1,2:5,6-dibenzanthracene
82. indeno(1,2,3-C,D) pyrene
83. pyrene
84. *2,3,7,8-tetrachlorodibenzo-p-dioxin (TCDD)
85. *tetrachloroethylene
86. *toluene
87. *trichloroethylene
88. *vinyl chloride (chloroethylene)

<u>Pesticides and Metabolites</u>

89. *aldrin
90. *dieldrin
91. *chlordane (technical mixture and metabolites)

*<u>DDT and metabolites</u>

92. 4,4'-DDT
93. 4,4'-DDE (p,p'-DDX)
94. 4,4'-DDD (p,p'-TDE)

*<u>endosulfan and metabolites</u>

95. alpha-endosulfan
96. beta-endosulfan
97. endosulfan sulfate

*<u>endrin and metabolites</u>

98. endrin
99. endrin aldehyde

*<u>heptachlor and metabolites</u>

100. heptachlor
101. heptachlor epoxide

*<u>hexachlorocyclohexane</u> (all insomers)

102. alpha-BHC
103. beta-BHC
104. gamma-BHC (lindane)

105. delta-BHC

*<u>polychlorinated biphenyls</u> (PCB's)

106. PCB-1242 (Arochlor 1242)
107. PCB-1254 (Arochlor 1254)

108. *Toxaphene

109. *Antimony (Total)
110. *Arsenic (Total)
111. *Asbestos (Fibrow)
112. *Beryllium (Total)
113. *Cadmium (Total)
114. *Chromium (Total)
115. *Copper (Total)
116. *Cyanide (Total)
117. *Lead (Total)
118. *Mercury (Total)
119. *Nickel (Total)
120. *Selenium (Total)
121. *Silver (Total)
122. *Thallium (Total)
123. *Zinc (Total)

SECTION XIII

PERFORMANCE FACTORS FOR TREATMENT PLANT OPERATIONS

General

In the past, some effluent requirements have been issued by regulatory agencies without stated concern for uniform expression. Some agencies have issued regulations without definition of time interval or without stipulation of the type of the sample (grab or composite). This has caused difficulties in determining whether a particular plant was in violation. To overcome that situation, daily historical data have been reviewed, when available, from several biological treatment plants.

Items such as spills, startup, shutdown, climatic conditions, storm runoff, flow variation and treatment plant inhibition may affect the operation of treatment plant performances.

Some factors that bring about variations in treatment plant performance can be minimized through proper dosing and operation. Some of the controllable causes of variability and techniques that can be used to minimize their effect are explained below.

Spills of certain materials in the plant can cause a heavy loading on the treatment system for a short period of time. A spill may not only cause higher effluent levels as it goes through the system, but may inhibit a biological treatment system and therefore have longer term effects. Equalization helps to lessen the effects of spills. However, long term reliable control can only be attained by an aggressive spill prevention and maintenance program including training of operating personnel. Industrial associations such as the Manufacturing Chemists Association (MCA) have developed guidelines for prevention, control and reporting of spills. These note how to assess the potential of spill occurrence and how to prevent spills. Each pharmaceutical plant should be aware of the MCA report and institute a program of spill prevention using the principles described in the report. If every plant were to use such guidelines as part of plant waste management control programs, its raw waste load and effluent variations would be decreased.

Startup and shutdown periods should be reduced to a minimum and their effect dampened through the use of equalization facilities and by proper scheduling of manufacturing cycles.

The design and choice of type of a treatment system should be based on the climate at the plant location so that this effect can be minimized. Where there are severe seasonal climatic conditions, the treatment system should be designed and sufficient operational flexibility should be available so that the system can function effectively. This may include air-supported flexible covers over aeration basins in cold climates to maintain relatively uniform temperature conditions for best performance.

Chemicals likely to inhibit the treatment processes should be identified and prudent measures taken to see that they do not enter the wastewater in concentrations that may result in treatment process inhibitions. Such measures include the diking of a chemical use area to contain spills and contaminated wash water, using dry instead of wet clean-up of equipment and changing to non-inhibiting chemicals.

The impact of process upsets and raw waste variations can be reduced by properly sized equalization units. Equalization is a retention of the wastes in a suitably designed and operated holding system to average out the influent before allowing it to enter the treatment system.

Storm water holding or diversion facilities should be designed on the basis of rainfall history and area being drained. The collected storm runoff can be drawn off at a constant rate to the treatment system. The volume of this contaminated storm runoff should be minimized through segregation and the prevention of contamination. Storm runoff from outside the plant area, as well as uncontaminated runoff, should be diverted around the plant or contaminated area.

Variations in the performance of wastewater treatment plants are attributable to one or more of the following:

1. Variations in sampling techniques.

2. Variations in analytical methods.

3. Variations in one or more operational parameters, e.g., the organic removal rate by the biological mass, settling rate changes of biological sludge

due to filamentous growths or non-settling pinpoint floc.

4. Changes in the treatability characteristics of the process wastewaters even after adequate equalization.

The wastewater treatment plant performance variations, which are due in part to changes in raw waste load and waste composition, will still occur although in lesser degree, even if provision is made for equalization of the influent.

To cope with occasional instances in which the final effluent exceeds a reasonably acceptable quality, it is proposed that unacceptable effluent be diverted to empty holding basins for re-treatment, instead of overdesigning the total system to accommodate unpredictable upsets.

Pharmaceutical Manufacturing

It is proposed that performance be judged by sampling the final effluent for a period of thirty consecutive days, averaging the BOD, COD and TSS results and expressing the results as percent reductions from average BOD_5, COD and TSS values found in treatment plant influent for the twelve months prior to the thirty consecutive days of effluent sampling.

TSS in unfiltered effluents may be expected to vary widely, due in part to hydraulic surges but primarily to uncertainties in the settling characteristics of the biological floc. Changes in waste composition, toxic substances, nutrient levels and dissolved oxygen content can affect bacterial metabolism, which is often evidenced by poor floc formation and separation. The upset condition may last for hours or days, until the bacteria adjust to the changed conditions. In filtered effluents, the TSS variations are reduced by trapping most of the solids in the filter media.

In order to establish variability factors for this point source category, historical data from plants number 8, 11, 14, 19, 22, 23 and 24 have been subjected to statistical analyses. The results of this effort are reported in Table XIII-3 for daily and monthly variability factors based on a 99 percent probability of occurrence.

Note that the compilation done in the initial study of exemplary plants using the median values instead of mean values is included for background purposes only and is shown in Table XIII-1. The summary values of the ratio of probability for 99/50 values for BOD_5, COD and TSS is presented in TAble XIII-2. The monthly BPT variability factors of 3.0 for BOD_5, 2.2 for COD and 3.0 for TSS which are utilized in the regulation published in the Federal Register are derived from Table XIII-2 and are modified based on a re-examination of data developed in Table XIII-3.

Table XIII -1

Exemplary Biological
Treatment Plant Performance

Pharmaceutical Industry

Plant No.	BOD5 Probability	BOD5 Max. Day[1] mg/L	BOD5 Max. Month Ave. mg/L	BOD5 Max Day / P_{50} Day	BOD5 Max Month / P_{50} Day	COD Probability	COD Max. Day[1] mg/L	COD Max. Month Ave. mg/L	COD Max Day / P_{50} Day	COD Max Month / P_{50} Day
11	P_{50}=51 mg/L					P_{50}=382 mg/L				
	P_{99}	402	144*	7.9	2.8	P_{99}	894	670	2.5	1.8
	P_{95}	194	124*	3.8	2.4	P_{95}	690	588	1.8	1.5
	P_{90}	162	110*	3.2	2 2	P_{90}	584	545	1.5	1.4
14	P_{50}=1.4 mg/L					P_{50}=16 8 mg/L				
	P_{99}	19.4	4.2	13.9	3.0	P_{99}	52 6	23.0*	3.1	1.4
	P_{95}	3.7	3.6	2.6	2.6	P_{95}	32.8	21.5*	2.0	1.3
	P_{90}	3.0	3.2	2.1	1.5	P_{90}	28.0	20.5*	1.7	1.2
05	P_{50}=8 mg/L					P_{50}=30 mg/L				
	P_{99}	29*	24*	3.6	3.0	P_{99}	162*	120*	5.4	4.0
	P_{95}	23*	20*	2.9	2 5	P_{95}	126*	98*	4.2	3.3
	P_{90}	20*	18*	2.5	2.2	P_{90}	108*	88*	3.6	2.9
19	P_{50}=100 mg/L									
	P_{99}	1115	222*	11.1	2.2					
	P_{95}	630	190*	6.3	1.9					
	P_{90}	431	175*	4.3	1.8					
04	P_{50}=310 mg/L									
	P_{99}	1667	830	5.4	2.7					
	P_{95}	812	698	2.6	2 2					
	P_{90}	711	625	2.3	2.0					
08	P_{50}=3.5 mg/L					P_{50}=32.6 mg/L				
	P_{99}	104	9*	29.7	2.6	P_{99}	202	88	6.2	2.7
	P_{95}	24	8*	6.9	2.3	P_{95}	124	75	3.7	2.3
	P_{90}	13	7*	3.7	2.0	P_{90}	68	68	2.1	2.1

Plant No.	TOC Probability	TOC Max. Day[1] mg/L	TOC Max. Month Ave. mg/L	TOC Max Day / P_{50} Day	TOC Max Month / P_{50} Day	TSS Probability	TSS Max. Day[1] mg/L	TSS Max. Month Ave. mg/L	TSS Max Day / P_{50} Day	TSS Max Month / P_{50} Day	Subcategory
11						P_{50}=53 mg/L					C
						P_{99}	320	132	6.0	2.5	
						P_{95}	188	114	3.5	2.2	
						P_{90}	143	104	2.7	2.0	
14						P_{50}=3.8 mg/L					E
						P_{99}	37.9	11.9*	10.0	3.1	
						P_{95}	20.0	10.0*	5.3	2.6	
						P_{90}	12.0	9.0*	3.2	2.4	
05						P_{50}=11 mg/L					D & E
						P_{99}	42*	39	3.8	3.5	
						P_{95}	36*	32	3.3	2.9	
						P_{90}	29*	28	2.6	2.5	
19	P_{50}=292 mg/L					P_{50}=147 mg/L					A & C
	P_{99}	1573	518*	5.3	1.8	P_{99}	2620	620*	17.8	4.2	
	P_{95}	862	465*	3.0	1.6	P_{95}	1557	520*	10.6	3.5	
	P_{90}	580	435*	2.0	1.5	P_{90}	802	460*	5.4	3.1	
04											A & C
08						P_{50}=21.5 mg/L					B
						P_{99}	56.0	39	2.6	1.8	
						P_{95}	46	34	2.1	1.6	
						P_{90}	40	31.5	1.9	1.5	

[1] P_{50} = Values are based upon daily data on long term basis

* Normalized Data

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Table XIII -2

Pharmaceutical Industry
Average Ratios of Probabilities of Occurrence

Ratio Of Probability	Daily	Monthly
	BOD_5	
99/50	10.9	3.0
95/50	4.1	2.3
90/50	3.1	2.0
	COD	
99/50	4.3	2.5
95/50	2.9	2.1
90/50	2.2	1.9
	TOC	
99/50	5.3	1.8
95/50	3.0	1.6
90/50	2.0	1.5
	TSS	
99/50	8.0	3.0
95/50	5.0	2.6
90/50	3.2	2.3

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TABLE XIII-3

Comparison of Daily and Monthly C_{99}/Ave. Factors for Pharmaceutical Plants

PLANT	MONTH	DIST.	DAILY	DIST.	DAILY/MO. RATIO
			BOD		
8	3.8	L	4.4	L	1.2
11	3.5	L	4.3	L	1.2
14	1.4	L	3.6	L	2.6
19	3.0	L	5.4	L	2.3
22	1.8	N	2.7	L-3	1.5
23	2.1	L-3	3.0	L-3	1.4
24	2.1	L-3	3.1	L-3	1.5
			COD		
8	3.0	L	3.4	L	1.1
11	1.9	L	2.1	L	1.1
14	1.9	L	2.4	L-3	1.3
19(TOC)	3.2	L	4.5	L	
22	1.7	N	1.8	N	1.1
23	1.6	N	2.8	L-3	1.7
24	2.0	L	2.2	L-3	1.1
			TSS		
8	2.9	L-3	3.6	L	1.2
11	3.2	L	4.3	L	1.3
14	1.5	N	4.0	L-3	2.6
19	5.8	L	5.8	L	1.0
22	1.8	N	2.9	L-3	1.6
23	2.3	L	3.5	L	1.5
24	1.9	L	2.8	L-3	1.5

	AVE. MO.	AVE. DAILY	AVE. RATIO	RATIO AVE.
BOD	2.4	3.8	1.7	1.6
COD	2.0	2.4	1.2	1.2
TSS	2.8	3.8	1.5	1.4

LEGEND:

N = Normal Distribution
L = Log Normal Distribution
L-3 = Three Parameter Log Normal Distribution

SECTION XIV

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SECTION XV

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2,699,451	1-11-55	Process for the Production of Organic Amino Diol Derivatives
2,694,089	11-9-54	Process for the Recovery of dl-Threo-1-p-Nitrophenyl-2-Amino-1,3-Propanediol
2,692,897	10-26-54	Process for the Production of Acylamido Diol Compounds
2,692,896	10-26-54	Process for the Production of N-Acylamido Diols
2,687,434	8-24-54	Production of 1-(Nitrophenyl)-z Acylamidopropane-1-3-Diols
2,686,802	8-17-54	Dichloracetimino Thioethers and Acid Addition Salts Thereof
2,681,364	6-15-54	Process for the Production of 1-p-Nitrophenyl-Z-Acylamidopropane-1,3-Diols
2,662,906	12-15-53	Chloramphenicol Esters and Method for Obtaining Same
2,568,571	9-18-51	Haloacetylamidophenyl-Halo-Acetamido propandiol
2,562,107	6-24-51	Derivatives of Organic Amino Alcohols and Methods for Obtaining the Same

2,546,762	3-27-51	Acylamino Acetophenones and Preparation Thereof
2,538,792	1-23-51	Preparation of Phenylserinol
2,538,766	1-23-51	Triacyl-Phenylpropane-aminodiols
2,538,765	1-23-51	Diacyl Phenylpropane-aminodiols
2,538,764	1-23-51	Acylamido-Phenylpropanediols
2,515,241	7-18-50	Nitrophenyl Acylamino Acy-loxy Ketones
2,515,239	7-18-50	a-Acylamido-p Hydroxy Nitro Substituted Propiophenones
2,514,376	7-11-50	Triacyl Nitrophenylpropane-aminodiols and Preparation Thereof
2,513,346	7-4-50	Process for Obtaining Organic Amino Diols
2,483,885	10-4-49	Nitrophenyl Acyl Amido Alkane Diols
2,483,884	10-4-49	Method for Making Nitrophe-nyl Acylamido Alkane Diols

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SECTION XVI

GLOSSARY

A. Pharmaceutical Industry

Active Ingredient. The chemical constituent in a medicinal which is responsible for its activity.

Alkaloids. Basic (alkaline) nitrogenous botanical products which produce a marked physiological action when administered to animals (or humans).

Alkylation. The addition of an aliphatic group to another molecule. The media in which this reaction is accomplished can be vapor or liquid phase, as well as aqueous or non-aqueous.

Ampules. A small glass container that can be sealed and its contents sterilized. Ampules are used to hold hypodermic solutions.

Antibiotic. A substance produced by a living organism which has the power to inhibit multiplication of, or to destroy, other organisms, especially bacteria.

Biological Products. In the pharmaceutical industry, medicinal products derived from animals or humans, such as vaccines, tosoids, antisera and human blood fractions.

Blood Fractionation. The separation of human blood into its various protein fractions.

Botanicals. Drugs made from a part of a plant, such as roots, bark, or leaves.

Capsules. A gelatinous shell used to contain medicinal chemicals and as a dosage form for administering medicine.

Disinfectant. A chemical agent which kills bacteria.

Ethical Products, Pharmaceuticals promoted by advertising to the medical, dental and veterinary professions.

Fermentor Broth. A slurry of microorganisms in water containing nutrients (carbohydrates, nitrogen) necessary for the microorganism's growth.

Fines. Crushed solids sufficiently fine to pass through a screen, etc.

Halogenated Solvent. An organic liquid chemcial containing an attached halogen (chlorine, flucrine, etc.) used for dissolving other substances.

Hormone. Any of a number of substances formed in the body which activate specifically receptive organs when transported to them by the body fluids. A material secreted by ductless glands (endocrine glands). Most hormones as well as synthetic analogues have in common the cyclopentanophenanthrene nucleus.

Injectables. Medicinals prepared in a sterile (buffered) form suitable for administration by injection.

Iso-Electric Precipitation. Adjustment of the pH (hydrogen ion concentration) of a solution to cause precipitation of a substance from the solution.

Medicament. Medicine or remedy.

Parenteral. Injection of substances into the body through any route other than via the digestive tract.

Plasma. The liquid part of the lymph and of the blood.

PMA. Pharmaceutical Manufacturing Association. The PMA represents 110 pharmaceutical manufacturing firms, who account for approximately 95 percent of the prescription products sold in the United States.

Proprietary Products. Pharmaceuticals promoted by advertising directly the the consumer.

Saprophytic Organism. One that lives on dead or decaying organic matter.

Serum. A fluid which is extracted from an animal rendered immune against a pathogenic organism and injected into a patient with the disease resulting from the same organism.

Steriod. Term applied to any one of a large group of substances chemically related to various alcohols found in plants and animals.

Toxoid. Toxin treated so as to destroy its toxicity, but still capable of inducing formation of antibodies.

Trypsinized. Hydrolyzed by trypsin, an enzyme in pancreatic juice.

Vaccine. A killed or modified live virus or bacteria prepared in suspension for inoculation to prevent or treat certain infectious diseases.

General Definitions

Abatement. The measures taken to reduce or eliminate pollution.

Absorption. A process in which one material (the absorbent) takes up and retains another (the absorbate) with the formation of a homogeneous mixture having the attributes of a solution. Chemical reaction may accompany or follow absorption.

Acclimation. The ability of an organism to adapt to changes in its immediate environment.

Acid. A substance which dissolves in water with the formation of hydrogen ions.

Acid Solution. A solution with a pH of less than 7.00 in which the activity of the hydrogen ion is greater than the activity of the hydroxyl ion.

Acidity. The capacity of a wastewater for neutralizing a base. It is normally associated with the presence of carbon dioxide, mineral and organic acids and salts of strong acids or weak bases. It is reported as equivalent of $CaCO_3$ because many times it is not known just what acids are present.

Acidulate. To make somewhat acidic.

Act. The Federal Water Pollution Control Act Amendments of 1972, Public Law 92-500.

Activated Carbon. Carbon which is treated by high-temperature heating with steam or carbon dioxide producing an internal porous particle structure.

Activated Sludge Process. A process which removes the organic matter from sewage by saturating it with air and biologically active sludge. The recycle "activated" microoganisms are able to remove both the soluble and colloidal organic material from the wastewater.

Adsorption. An advanced method of treating wastes in which a material removes organic matter not necessarily responsive to clarification or biological treatment by adherence on the surface of solid bodies.

Adsorption Isotherm. A plot used in evaluating the effectiveness of activated carbon treatment by showing the amount of impurity adsorbed versus the amount remaining. They are determined at a constant temperature by varying the amount of carbon used or the concentration of the impurity in contact with the carbon.

Advance Waste Treatment. Any treatment method or process employed following biological treatment to increase the removal of pollution load, to remove substances that may be deleterious to receiving waters or the environment or to produce a high-quality effluent suitable for reuse in any specific manner or for discharge under critical conditions. The term tertiary treatment is commonly used to denote advanced waste treatment methods.

Aeration. (1) The bringing about of intimate contact between air and a liquid by one of the following methods: spraying the liquid in the air, bubbling air through the liquid, or agitation of the liquid to promote surface absorption of air. (2) The process or state of being supplied or impregnated with air; in waste treatment, a process in which liquid from the primary clarifier is mixed with compressed air and with biologically active sludge.

Aeration Period. (1) The theoretical time, usually expressed in hours, that the mixed liquor is subjected to aeration in an aeration tank undergoing activated-sludge treatment. It is equal to the volume of the tank divided by the volumetric rate of flow of wastes and return sludge. (2) The theoretical time that liquids are subjected to aeration.

Aeration Tank. A vessel for injecting air into the water.

Aerobic. Ability to live, grow, or take place only where free oxygen is present.

Aerobic Biological Oxidation. Any waste treatment or process utilizing aerobic organisms, in the presence of air or oxygen, as agents for reducing the pollution load or oxygen demand of organic substances in waste.

Aerobic Digestion. A process in which microorganisms obtain energy by endogenous or auto-oxidation of their cellular protoplasm. The biologically degradable constituents of cellular material are slowly oxidized to carbon dioxide, water and ammonia, with the ammonia being further converted into nitrates during the process.

Algae. One-celled or many-celled plants which grow in sunlit waters and which are capable of photosynthesis. They are a food for fish and small aquatic animals and, like all plants, put oxygen in the water.

Algicide. Chemical agent used to destroy or control algae.

Alkali. A water-soluble metallic hydroxide that ionizes strongly.

Alkalinity. The presence of salts of alkali metals. The hydroxides, carbonates and bicarbonates of calcium, sodium and magnesium are common impurities that cause alkalinity. A quantitative measure of the capacity of liquids or suspensions to neutralize strong acids or to resist the establishment of acidic conditions. Alkalinity results from the presence of bicarbonates, carbonates, hydroxides, alkaline, salts and occasionally borates and is usually expressed in terms of the amount of calcium carbonate that would have an equivalent capacity to neutralize strong acids.

Alum. A hydrated aluminum sulfate or potassium aluminum sulfate or ammonium aluminum sulfate which is used as a settling agent. A coagulant.

Ammonia Nitrogen. A gas released by the microbiological decay of plant and animal proteins. When ammonia nitrogen is found in waters, it is indicative of incomplete treatment.

Ammonia Stripping. A modification of the aeration process for removing gases in water. Ammonium ions in wastewater exist in equilibrium with ammonia and hydrogen ions. As pH increases, the equilibrium shifts to the right and above pH 9 ammonia may be liberated as a gas by agitating the wastewater in the presence of air. This is usually done in a packed tower with an air blower.

Ammonification. The process in which ammonium is liberated from organic compounds by microooganisms.

Anaerobic. Ability to live, grow, or take place where there is no air or free oxygen present.

Anaerobic Biological Treatment. Any treatment method or process utilizing anaerobic or facultative organisms, in the absence of air, for the purpose of reducing the organic matter in wastes or organic solids settled out from wastes.

Anaerobic Digestion. Biodegradable materials in primary and excess activated sludge are stabilized by being oxidized to carbon dioxide, methane and other inert products. The primary digester serves mainly to reduce VSS, while the secondary digester is mainly for solids-liquid separation, sludge thickening and storage.

Anion. Ion with a negative charge.

Antagonistic Effect. The simultaneous action of separate agents mutually opposing each other.

Antibiotic. A substance produced by a living organism which has power to inhibit the multiplication of, or to destroy, other organisms, especially bacteria.

Aqueous Solution. One containing water or watery in nature.

Aquifer. A geologic formation or stratum that contains water and transmits it from one point to another in quantities sufficient to permit economic development (capable of yielding an appreciable supply of water).

Aqueous Solution. One containing water or watery in nature.

Arithmetic Mean. The arithmetic mean of a number of items is obtained by adding all the items together and dividing the total by the number of items. It is frequently called the average. It is greatly affected by extreme values.

Autoclave. A heavy vessel with thick walls for conducting chemical reactions under high pressure. Also an apparatus using steam under pressure for sterilization.

Azeotrope. A liquid mixture that is characterized by a constant minimum or maximum boiling point which is lower or higher than that of any of the components and that distills without change in composition.

Backwashing. The process of cleaning a rapid sand or mechanical filter by reversing the flow of water.

Bacteria. Unicellular, plant-like microorganisms, lacking chlorophyll. Any water supply contaminated by sewage is certain to contain a bacterial group called "coliform".

Bateria, Coliform Group. A group of bacteria, predominantly inhabitants of the intestine of man but also found on vegetation, including all aerobic and facultative anaerobic gram-negative, non-sporeforming bacilli that ferment lactose with gas formation. This group includes five tribes of which the very great majority are Eschericheae. The Eschericheae tribe comprises three genera and ten species, of which Escherichia Coli and Aerobacter Aerogenes are dominant. The Escherichia Coli are normal inhabitants of the intestine of man and all vertbrates whereas Aerobacter Aerogenes normally are found on grain and plants and only to a varying degree in the intestine of man and animals. Formerly referred to as B. Coli, B. Coli group and Coli-Aerogenes Group.

Bacterial Growth. All bacteria require food for their continued life and growth and all are affected by the conditions of their environment. Like human beings, they consume food, they respire, they need moisture, they require heat and they give off waste products. Their food requirements are very definite and have been, in general, already outlined. Without an adequate food supply of the type the specific organism requires, bacteria will not grow and multiply at their maximum rate and they will therefore, not perform their full and complete functions.

BADCT (NSPS) Effluent Limitations. Limitations for new sources which are based on the application of the Best Available Demonstrated Control Technology.

Base. A substance that in aqueous solution turns red litmus blue, furnishes hydroxyl ions and reacts with an acid to form a salt and water only.

Batch Process. A process which has an intermittent flow of raw materials into the process and a resultant intermittent flow of product from the process.

BAT (BATEA) Effluent Limitations. Limitations for point sources, other than publicly owned treatment works, which are based on the application of the Best Available Technology Economically Achievable. These limitations must be achieved by July 1, 1983.

Benthic. Attached to the bottom of a body of water.

Benthos. Organisms (fauna and flora) that live on the bottoms of bodies of water.

Bioassay. An assessment which is made by using living organisms as the sensors.

Biochemical Oxygen Demand (BOD). A measure of the oxygen required to oxidize the organic material in a sample of wastewater by natural biological process under standard conditions. This test is presently universally accepted as the yardstick of pollution and is utilized as a means to determine the degree of treatment in a waste treatment process. Usually given in mg/l (cr ppm units), meaning milligrams of oxygen required per liter of wastewater, it can also be expressed in pounds of total oxygen required per wastewater or sludge batch. The standard BOD is five days at 20 degrees C.

Biota. The flora and fauna (plant and animal life) of a stream or other water body.

Biological Treatment System. A system that uses microorganisms to remove organic pollutant material from a wastewater.

Blowdown. Water intentionally discharged from a cooling or heating system to maintain the dissolved solids concentration of the circulating water below a specific critical level. The removal of a portion of any process flow to maintain the constituents of the flow within desired levels. Process may be intermittent or continuous. 2) The water discharged from a boiler or cooling tower to dispose of accumulated salts.

BOD5. Biochemical Oxygen Demand (BOD) is the amount of oxygen required by bacteria while stabilizing decomposable organic matter under aerobic conditions. The BOD test has been developed on the basis of a 5-day incubation period (i.e. BOD5).

Boiler Blowdown. Wastewater resulting from purging of solid and waste materials from the boiler system. A solids build up in concentration as a result of water evaporation (steam generation) in the boiler.

BPT (BPCTCA) Effluent Limitations. Limitations for point sources, other than publicly owned treatment works, which are based on the application of the Best Practicable Control Technology Currently Available. These limitations must be achieved by July 1, 1977.

Break Point. The point at which impurities first appear in the effluent of a granular carbon adsorption bed.

Break Point Chlorination. The addition of sufficient chlorine to destroy or oxidize all substances that creates a chlorine demand with an excess amount remaining in the free residual state.

Brine. Water saturated with a salt.

Buffer. A solution containing either a weak acid and its salt or a weak base and its salt which thereby resists changes in acidity or basicity, resists changes in pH.

Carbohydrate. A compound of carbon, hydrogen and oxygen, usually having hydrogen and oxygen in the proportion of two to one.

Carbonaceous. Containing or composed of carbon.

Catalyst. A substance which changes the rate of a chemical reaction but undergoes no permanent chemical change itself.

Cation. The ion in an electrolyte which carries the positive charge and which migrates toward the cathode under the influence of a potential difference.

Caustic Soda. In its hydrated form it is called sodium hydroxide. Soda ash is sodium carbonate.

Cellulose. The fibrous constituent of trees which is the principal raw material of paper and paperboard. Commonly thought of as a fibrous material of vegetable origin.

Centrate. The liquid fraction that is separated from the solids fraction of a slurry through centrifugation.

Centrifugation. The process of separating heavier materials from lighter ones through the employment of centrifugal force.

Centrifuge. An apparatus that rotates at high speed and by centrifugal force separates substances of different densities.

Chemical Oxygen Demand (COD). A measure of oxygen-consuming capacity of organic and inorganic matter present in water or wastewater. It is expressed as the amount of oxygen consumed from a chemical oxidant in a specific test. It does not differentiate between stable and unstable organic matter and thus does not correlate with biochemical oxygen demand.

Chemical Synthesis. The processes of chemically combining two or more constituent substances into a single substance.

Chlorination. The application of chlorine to water, sewage or industrial wastes, generally for the purpose of disinfection but frequently for accomplishing other biological or chemical results.

Clarification. Process of removing turbidity and suspended solids by settling. Chemicals can be added to improve and speed up the settling process through coagulation.

Clarifier. A basin or tank in which a portion of the material suspended in a wastewater is settled.

Clays. Aluminum silicates less than 0.002mm (2.0 um) in size. Therefore, most clay types can go into colloidal suspension.

Coagulation. The clumping together of solids to make them settle out of the sewage faster. Coagulation of solids is brought about with the use of certain chemicals, such as lime, alum or polyelectrolytes.

Coagulation and Flocculation. Processes which follow sequentially.

Coagulation Chemicals. Hydrolyzable divalent and trivalent metallic ions of aluminum, magnesium and iron salts. They include alum (aluminum sulfate), quicklime (calcium oxide), hydrated lime (calcium hydroxide), sulfuric acid, anhydrous ferric chloride. Lime and acid affect only the solution pH which in turn causes coagulant precipitation, such as that of magnesium.

Coliform. Those bacteria which are most abundant in sewage and in streams containing feces and other bodily waste discharges. See bacteria, coliform group.

Coliform Organisms. A group of bacteria recognized as indicators of fecal pollution.

Colloid. A finely divided dispersion of one material (0.01-10 micron-sized particles), called the "dispersed phase" (solid), in another material, called the "dispersion medium" (liquid).

Color Bodies. Those complex molecules which impart color to a solution.

Color Units. A solution with the color of unity contains a mg/l of metallic platinum (added as potassium chloroplatinate to distilled water). Color units are defined against a platinum-cobalt standard and are based, as are all the other water quality criteria, upon those analytical methods described in Standard Methods for the Examination of Water and Wastewater, 12 ed., Amer. Public Health Assoc., N.Y., 1967.

Combined Sewer. One which carries both sewage and storm water run-off.

Composite Sample. A combination of individual samples of wastes taken at selected intervals, generally hourly for 24 hours, to minimize the effect of the variations in individual samples. Individual samples making up the composite may be of equal volume or be roughly apportioned to the volume of flow of liquid at the time of sampling.

Composting. The biochemical stabilization of solid wastes into a humus-like substance by producing and controlling an optimum environment for the process.

Concentration. The total mass of the suspended or dissolved particles contained in a unit volume at a given temperature and pressure.

Conductivity. A reliable measurement of electrolyte concentration in a water sample. The conductivity measurement can be related to the concentration of dissolved solids and is almost directly proportional to the ionic concentration of the total electrolytes.

Contact Stabilization. Aerobic digestion.

Contact Process Wastewaters. These are process-generated wastewaters which have come in direct or indirect contact with the reactants used in the process. These include such streams as contact cooling water, filtrates, centrates, wash waters, etc.

Continuous Process. A process which has a constant flow of raw materials into the process and resultant constant flow of product from the process.

Contract Disposal. Disposal of waste products through an outside party for a fee.

Cooling Water - Uncontaminated. Water used for cooling purposes only which has no direct contact with any raw material, intermediate, or final product and which does not contain a level of contaminants detectably higher than that of the intake water.

Cooling Water - Contaminated. Water used for cooling purposes only which may become contaminated either through the use of water treatment chemicals used for corrosion inhibitors or biocides, or by direct contact with process materials and/or wastewater.

Crustaceae. These are small animals ranging in size from 0.2 to 0.3 millimeters long which move very rapidly through the water in search of food. They have recognizable head and posterior sections. They form a principal source of food for small fish and are found largely in relatively fresh natural water.

Cryogenic. Having to do with extremely low temperatures.

Crystallization. The formation of solid particles within a homogeneous phase. Formation of crystals separates a solute from a solution and generally leaves impurities behind in the mother liquid.

Culture. A mass of microorganisms growing in a media.

Curie. 3.7×10^{10} disintegrations per second within a given quantity of material.

Cyanide, Total. Total cyanide as determined by the test procedure specified in 40 CFR Part 136 (Federal Register, Vol. 38, no. 199, October 16, 1973).

Cyclone. A conical shaped vessel for separating either entrained solids or liquid materials from the carrying air or vapor. The vessel has a tangential entry nozzle at or near the largest diameter, with an overhead exit for air or vapor and a lower exit for the more dense materials.

Cyanide A. Cyanides amendable to chlorination as described in "1972 Annual Book of ASTM Standards" 1972: Standard D 2036-72, Method B, p. 553.

Degreasing. The process of removing greases and oils from sewage, waste and sludge.

Demineralization. The total removal of all ions.

Denitrification. Bacterial mediated reduction of nitrate to nitrite. Other bacteria may act on the nitrite reducing it to ammonia and finally N2 gas. This reduction of nitrate occurs under anaerobic conditions. The nitrate replaces oxygen as an electron acceptor during the metabolism of carbon compounds under anaerobic conditions. A biological process in which gaseous nitrogen is produced from nitrite and nitrate. The heterotrophic microoganisms which participate in this process include pseudomonades, achromobacters and bacilli.

Derivative. A substance extracted from another body or substance.

Desorption. The opposite of adsorption. A phenomenon where an adsorbed molecule leaves the surface of the adsorbent.

Diluent. A diluting agent.

Disinfection. The process of killing the larger portion (but not necessarily all) of the harmful and objectionable microorganisms in or on a medium.

Dissolved Air Flotation. The term "flotation" indicates something floated on or at the surface of a liquid. Dissolved air flotation thickening is a process that adds energy in the form of air bubbles, which become attached to suspended sludge particles, increasing the buoyancy of the particles and producing more positive flotation.

Dissolved Oxygen (DO). The oxygen dissolved in sewage, water or other liquids, usually expressed either in milligrams per liter or percent of saturation. It is the test used in BOD determination.

Distillation. The separation, by vaporization, of a liquid mixture of miscible and volatile substance into individual components, or, in some cases, into a group of components. The process of raising the temperature of a liquid to the boiling point and condensing the resultant vapor to liquid form by cooling. It is used to remove substances from a liquid or to obtain a pure liquid from one which contains impurities or which is a mixture of several liquids having different boiling temperatures. Used in the treatment of fermentation products, yeast, etc. and other wastes to remove recoverable products.

Double-effect Evaporators. Double-effect evaporators are two evaporators in series where the vapors from one are used to boil liquid in the other.

DO Units. The units of measurement used are milligrams per liter (mg/l) and parts per million (ppm), where mg/l is defined as the actual weight of oxygen per liter of water and ppm is defined as the parts actual weight of oxygen dissolved in a million parts weight of water, i.e., a pound of oxygen in a million pounds of water is 1 ppm. For practical purposes in pollution control work, these two are used interchangeably; the density of water is so close to 1 g/ccu m that the error is negligible. Similarly, the changes in volume of oxygen with changes in temperature are insignificant. This, however, is not true if sensors are calibrated in percent saturation rather than in mg/l or ppm. In that case, both temperature and barometric pressure must be taken into consideration.

Drift. Entrained water carried from a cooling device by the exhaust air.

Dual Media. A deep-bed filtration system utilizing two separate and discrete layers of dissimilar media (e.g., anthracite and sand) placed one on top of the other to perform the filtration function.

Ecology. The science of the interrelations between living organisms and their environment.

Effluent. A liquid which leaves a unit operation or process. Sewage, water or other liquids, partially or completely treated or in their natural states, flowing out of a reservoir basin, treatment plant or any other unit operation. An influent is the incoming stream.

Elution. (1) The process of washing out, or removing with the use of a solvent. (2) In an ion exchange process it is defined as the stripping of adsorbed ions from an ion exchange resin by passing through the resin solutions containing other ions in relatively high concentrations.

Elutriation. A process of sludge conditioning whereby the sludge is washed, either with fresh water or plant effluent, to reduce the sludge alkalinity and fine particles, thus decreasing the amount of required coagulant in further treatment steps, or in sludge dewatering.

Emulsion. Emulsion is a suspension of fine droplets of one liquid in another.

Entrainment Separator. A device to remove liquid and/or solids from a gas stream. Energy source is usually derived from pressure drop to create centrifugal force.

Environment. The sum of all external influences and conditions affecting the life and the development of an organism.

Equalization Basin. A holding basin in which variations in flow and composition of a liquid are averaged. Such basins are used to provide a flow of reasonably uniform volume and composition to a treatment unit.

Esterification. This generally involves the combination of an alcohol and an organic acid to produce an ester and water The reaction is carried out in the liquid phase, with aqueous sulfuric acid as the catalyst. The use of sulfuric acid has in the past caused this type of reaction to be called sulfation.

Eutrophication. The process in which the life-sustaining quality of a body of water is lost or diminished (e.g., aging or filling in of lakes). A eutrophic condition is one in which the water is rich in nutrients but has a seasonal oxygen deficiency.

Evapotranspiration. The loss of water from the soil both by evaporation and by transpiration from the plants growing thereon.

Facultative. Having the power to live under different conditons (either with or without oxygen).

Facultative Lagoon. A combination of the aerobic and anaerobic lagoons. It is divided by loading and thermal stratifications into an aerobic surface and an anaerobic bottom, therefore the principles of both the aerobic and anaerobic processes apply.

Fatty Acids. An organic acid obtained by the hydrolysis (saponification) of natural fats and oils, e.g., stearic and palmitic acids. These acids are monobasic and may or may not contain some double bonds. They usually contain sixteen or more carbon atoms.

Fauna. The animal life adapted for living in a specified environment.

Fermentation. Oxidative decomposition of complex substances through the action of enzymes or ferments produced by microorganisms.

Filter Cakes. Wet solids generated by the filtration of solids from a liquid. This filter cake may be a pure material (product) or a waste material containing additional fine solids (i.e., diatomaceous earth) that has been added to aid in the filtration.

Filter, Trickling. A filter consisting of an artificial bed of coarse material, such as broken stone, clinkers, slate, slats or brush, over which sewage is distributed and applied in drops, films for spray, from troughs, drippers, moving distributors or fixed nozzles. The sewage trickles through to the underdrains and has the opportunity to form zoogleal slimes which clarify and oxidize the sewage.

Filter, Vacuum. A filter consisting of a cylindrical drum mounted on a horizontal axis and covered with a filter cloth. The filter revolves with a partial submergence in the liquid, and a vacuum is maintained under the cloth for the larger part of each revolution to extract moisture. The cake is scraped off continuously.

Filtrate. The liquid fraction that is separated from the solids fraction of a slurry through filtration.

Filtration, Biological. The process of passing a liquid through a biological filter containing media on the surfaces of which zoogleal films develop that absorb and adsorb fine suspended, colloidal and dissolved solids and that release various biochemical end products.

Flocculants. Those water-soluble organic polyelectrolytes that are used alone or in conjunction with inorganic coagulants such as lime, alum or ferric chloride or coagulant aids to agglomerate solids suspended in aqueous systems or both, The large dense flocs resulting from this process permit more rapid and more efficient solids-liquid separations.

Flocculation. The formation of flocs. The process step following the coagulation-precipitation reactions which consists of bringing together the colloidal particles. It is the agglomeration by organic polyelectroytes of the small, slowly settling flocs formed during coagulation into large flocs which settle rapidly.

Flora. The plant life characteristic of a region.

Flotation. A method of raising suspended matter to the surface of the liquid in a tank as scum-by aeration, vacuum, evolution of gas, chemicals, electrolysis, heat or bacterial decomposition and the subsequent removal of the scum by skimming.

Fractionation (or Fractional Distillation). The separation of constituents, or group of constituents, of a liquid mixture of miscible and volatile substances by vaporization and recondensing at specific boiling point ranges.

Fungus. A vegetable cellular organism that subsists on organic material, such as bacteria.

Gland. A device utilizing a soft wear-resistant material used to minimize leakage between a rotating shaft and the stationary portion of a vessel such as a pump.

Gland Water. Water used to lubricate a gland. Sometimes called "packing water."

Grab Sample. (1) Instantaneous sampling. (2) A sample taken at a random place in space and time.

Grease. In sewage, grease includes fats, waxes, free fatty acids, calcium and magnesium soaps, mineral oils and other nonfatty materials. The type of solvent to be used for its extraction should be stated.

Grit Chamber. A small detention chamber or an enlargement of a sewer designed to reduce the velocity of flow of the liquid and permit the separation of mineral from organic solids by differential sedimentation.

Groundwater. The body of water that is retained in the saturated zone which tends to move by hydraulic gradient to lower levels.

Hardness. A measure of the capacity of water for precipitating soap. It is reported as the hardness that would be produced if a certain amount of $CaCO_3$ were dissolved in water. More than one ion contributes to water hardness. The "Glossary of Water and Wastewater Control Engineering" defines hardness as: A characteristic of water, imparted by salts of calcium, magnesium and ion, such as bicarbonates, carbonates, sulfates, chlorides and nitrates, that causes curdling of soap, deposition of scale in boilers, damage in some industrial processes, and sometimes objectionable taste. Calcium and magnesium are the most significant constituents.

Heavy Metals. A general name given for the ions of metallic elements, such as copper, zinc, iron, chromium and aluminum. They are normally removed from a wastewater by the formation of an insoluble precipitate (usually a metallic hydroxide).

Hydrocarbon. A compound containing only carbon and hydrogen.

Hydrolysis. A chemical reaction in which water reacts with another substance to form one or more new substances.

Incineration. The combustion (by burning) of organic matter in wastewater sludge.

Incubate. To maintain cultures, bacteria, or other microorganisms at the most favorable temperature for development.

Influent. Any sewage, water or other liquid, either raw or partly treated, flowing into a reservoir, basin, treatment plant, or any part thereof. The influent is the stream entering a unit operation; the effluent is the stream leaving it.

In-Plant Measures. Technology applied within the manufacturing process to reduce or eliminate pollutants in the raw waste water. Sometimes called "internal measures" or "internal controls".

Ion. An atom or group of atoms possessing an electrical charge.

Ion Exchange. A reversible interchange of ions between a liquid and a solid involving no radical change in the structure of the solid. The solid can be a natural zeolite or a synthetic resin, also called polyelectrolyte. Cation exchange resins exchange their hydrogen ions for metal cations in the liquid. Anion exchange resins exchange their hydroxyl ions for anions such as nitrates in the liquid. When the ion-retaining capacity of the resin is exhausted, it must be regenerated. Cation resins are regenerated with acids and anion resins with bases.

Lagoons. An oxidation pond that received sewage which is not settled or biologically treated.

LC 50. A lethal concentration for 50% of test animals. Numerically the same as TLm. A statistical estimate of the toxicant, such as pesticide concentration, in water necessary to kill 50% of the test organisms within a specified time under standardized conditions (usually 24,48 or 96 hr).

Leach. To dissolve out by the action of a percolating liquid, such as water, seeping through a sanitary landfill.

Lime. Limestone is an accumulation of organic remains consisting mostly of calcium carbonate. When burned, it yields lime which is a solid. The hydrated form of a chemical lime is calcium hydroxide.

Liquid-liquid-extraction. The process by which the constituents of a solution are separated by causing their unequal distribution between two insoluble liquids.

Maximum Day Limitation. The effluent limitation value equal to the maximum for one day and is the value to be published by the EPA in the Federal Register.

Maximum Thirty Day Limitation. The effluent limitation value for which the average of daily values for thirty consecutive days shall not exceed and is the value to be published by the EPA in the Federal Register.

Mean. The arithmetic average of the individual sample values.

Median. In a statistical array, the value having as many cases larger in value as cases smaller in value.

Median Lethal Dose (LD50). The dose lethal to 50 percent of a group of test organisms for a specified period. The dose material may be ingested or injected.

Median Tolerance Limit (TLm). In toxicological studies, the concentration of pollutants at which 50 percent of the test animals can survive for a specified period of exposure.

Microbial. Of or pertaining to a pathogenic bacterium.

Molecular Weight. The relative weight of a molecule compared to the weight of an atom of carbon taken as exactly 12.00; the sum of the atomic weights of the atoms in a molecule.

Mycelia. The mass of filaments which constitutes the vegetative body of fungi.

Navigable Waters. Includes all navigable waters of the United States; tributaries of navigable waters; interstate waters; intrastate lakes, rivers and streams which are utilized by interstate travellers for recreational or other purposes; intrastate lakes, rivers and streams from which fish or shellfish are taken and sold in interstate commerce; and intrastate lakes, rivers and streams which are utilized for industrial purposes by industries in interstate commerce.

Neutralization. The restoration of the hydrogen or hydroxyl ion balance in a solution so that the ionic concentration of each are equal. Conventionally, the notation "pH" (puissance d'hydrogen) is used to describe the hydrogen ion concentration or activity present in a given solution. For dilute solutions of strong acids, i.e., acids which are considered to be completely dissociate (ionized in solution), activity equals concentration.

New Source. Any facility from which there is or may be a discharge of pollutants, the construction of which is commenced after the publication of proposed regulations prescribing a standard of performance under section 306 of the Act.

Nitrate Nitrogen. The final decomposition product of the organic nitrogen compounds. Determination of this parameter indicates the degree of waste treatment.

Nitrification. Bacterial mediated oxidation of ammonia to nitrite. Nitrite can be further oxidized to nitrate. These reactions are brought about by only a few specialized bacterial species. Nitrosomonias sp. and Nitrococcus sp. oxidize ammonia to nitrite which is oxidized to nitrate by Nitrobacter sp.

Nitrifiers. Bacteria which causes the oxidation of ammonia to nitrites and nitrates.

Nitrite Nitrogen. An intermediate stage in the decomposition of organic nitrogen to the nitrate form. Tests for nitrite nitrogen can determine whether the applied treatment is sufficient.

Nitrobacteria. Those bacteria (an autotrophic genus) that oxidize nitrite nitrogen to nitrate nitrogen.

Nitrogen Cycle. Organic nitrogen in waste is oxidized by bacteria into ammonia. If oxygen is present, ammonia is bacterially oxidized first into nitrite and then into nitrate. If oxygen is not present, nitrite and nitrate are bacterially reduced to nitrogen gas. The second step is called "denitrification."

Nitrogen Fixation. Biological nitrogen fixation is carried on by a selected group of bacteria which take up atmospheric nitrogen and convert it to amine groups or for amino acid synthesis.

Nitrosomonas. Bacteria which oxidize ammonia nitrogen into nitrite nitrogen; an aerobic autotrophic life form.

Non-contact Cooling Water. Water used for cooling that does not come into direct contact with any raw material, intermediate product, waste product or finished product.

Non-contact Process Wastewaters. Wastewaters generated by a manufacturing process which have not come in direct contact with the reactants used in the process. These include such streams as non-contact cooling water, cooling tower blowdown, boiler blowdown, etc.

Nonputrescible. Incapable of organic decomposition or decay.

Normal Solution. A solution that contains 1 gm molecular weight of the dissolved substance divided by the hydrogen equivalent of the substance (that is, one gram equivalent) per liter of solution. Thus, a one normal solution of sulfuric acid (H_2SO_4, mol. wt. 98) contains (98/2) 49gms of H_2SO_4 per liter.

NSPS. New Source Performance Standards. See BADCT.

NPDES. National Pollution Discharge Elimination System. A federal program requiring industry to obtain permits to discharge plant effluents to the nation's water courses.

Nutrient. Any substance assimilated by an organism which promotes growth and replacement of cellular constituents.

Operations and Maintenance. Costs required to operate and maintain pollution abatement equipment including labor, material, insurance, taxes, solid waste disposal, etc.

Organic Loading. In the activated sludge process, the food to micoorganisms (F/M) ratio defined as the amount of biodegradable material available to a given amount of microorganisms per unit of time.

Osmosis. The diffusion of a solvent through a semipermeable membrane into a more concentrated solution.

Oxidation. A process in which an atom or group of atoms loses electrons; the combination of a substance with oxygen, accompanied with the release of energy. The oxidized atom usually becomes a positive ion while the oxidizing agent becomes a negative ion in (chlorination for example).

Oxidation Pond. A man-made lake or body of water in which wastes are consumed by bacteria. It receives an influent which has gone through primary treatment while a lagoon receives raw untreated sewage.

Oxidation Reduction (OR). A class of chemical reactions in which one of the reacting species gives up electrons (oxidation) while another species in the reaction accepts electrons (reduction). At one time, the term oxidation was restricted to reactions involving hydrogen. Current chemical technology has broadened the scope of these terms to include all reactions where electrons are given up and taken on by reacting species; in fact, the donating and accepting of electrons must take place simultaneously.

Oxidation Reduction Potential (ORP). A measurement that indicates the activity ratio of the oxidizing and reducing species present.

Oxygen, Available. The quantity of atmospheric oxygen dissolved in the water of a stream; the quantity of dissolved oxygen available for the oxidation of organic matter in sewage.

Oxygen, Dissolved. The oxygen (usually designated as DO) dissolved in sewage, water or another liquid and usually expressed in parts per million or percent of saturation.

Ozonation. A water or wastewater treatment process involving the use of ozone as an oxidation agent.

Ozone. That molecular oxygen with three atoms of oxygen forming each molecule. The third atom of oxygen in each molecule of ozone is loosely bound and easily released. Ozone is used sometimes for the disinfection of water but more frequently for the oxidation of taste-producing substances, such as phenol, in water and for the neutralization of odors in gases or air.

Parts Per Million (ppm). Parts by weight in sewage analysis; ppm by weight is equal to milligrams per liter divided by the specific gravity. It should be noted that in water analysis ppm is always understood to imply a weight/weight ratio, even though in practice a volume may be measured instead of a weight.

Pathogenic. Disease producing.

Percolation. The movement of water beneath the ground surface both vertically and horizontally, but above the groundwater table.

Permeability. The ability of a substance (soil) to allow appreciable movement of water through it when saturated and actuated by a hydrostatic pressure.

pH. The negative logarithm of the hydrogen ion concentration or activity in a solution. The number 7 indicates neutrality, numbers less than 7 indicate increasing acidity and numbers greater than 7 indicate increasing alkalinity.

Phenol. Class of cyclic organic derivatives with the basic chemical formula C6H5OH.

Phosphate. Phosphate ions exist as an ester or salt of phosphoric acid, such as calcium phosphate rock. In municipal wastewater, it is most frequently present as orthophosphate.

Phosphorus Precipitation. The addition of the multivalent metallic ions of calcium, iron and aluminum to wastewater to form insoluble precipitates with phosphorus.

Photosynthesis. The mechanism by which chlorophyll-bearing plant utilize light energy to produce carbohydrate and oxygen from carbon dioxide and water (the reverse of respiration).

Physical/Chemical Treatment System. A system that utilizes physical (i.e., sedimentation, filtration, centrifugation, activated carbon, reverse osmosis, etc.) and/or chemical means (i.e., coagulation, oxidation, precipitation, etc.) to treat wastewaters.

Point Source. Any discernible, confined and discrete conveyance, including but not limited to any pipe, ditch, channel, tunnel, conduit, well, discrete fissure, container, rolling stock, concentrated animal feeding operation, or vessel or other floating craft, from which pollutants are or may be discharged.

Pollutional Load. A measure of the strength of a wastewater in terms of its solids or oxygen-demanding characteristics or other objectionable physical and chemical characteristics or both or in terms of harm done to receiving waters. The pollutional load imposed on sewage treatment works is expressed as equivalent population.

Polyelectrolytes. Synthetic chemicals (polymers) used to speed up the removal of solids from sewage. These chemicals cause solids to coagulate or clump together more rapidly than do chemicals such as alum or lime. They can be anionic (-charge), nonionic (+ and -charge) or cationic (+charge--the most popular). They are linear or branched organic polymers. They have high molecular weights and are water-soluble. Compounds similar to the polyelectrolyte flocculants include surface-active agents and ion exchange resins. The former are low molecular weight, water soluble compounds used to disperse solids in aqueous systems. The latter are high molecular weight, water-insoluble compounds used to selectively replace certain ions already present in water with more desirable or less noxious ions.

Population Equivalent (PE). An expression of the relative strength of a waste (usually industrial) in terms of its equivalent in domestic waste, expressed as the population that would produce the equivalent domestic waste. A population equivalent of 160 million persons means the pollutional effect equivalent to raw sewage from 160 million persons; 0.17 pounds BOD (the oxygen demand of untreated wastes from one person) = 1 PE.

Potable Water. Drinking water sufficiently pure for human use.

Potash. Potassium compounds used in agriculture and industry. Potassium carbonate can be obtained from wood ashes. The mineral potash is usually a muriate. Caustic potash is its hydrated form.

Preaeration. A preparatory treatment of sewage consisting of aeration to remove gases and add oxygen or to promote the flotation of grease and aid coagulation.

Precipitation. The phenomenon which occurs when a substance held in solution passes out of that solution into solid form. The adjustment of pH can reduce solubility and cause precipitation. Alum and lime are frequently used chemicals in such operations as water softening or alkalinity reduction.

Pretreatment. Any wastewater treatment process used to partially reduce the pollution load before the wastewater is introduced into a main sewer system or delivered to a treatment plant for substantial reduction of the pollution load.

Primary Clarifier. The settling tank into which the wastewater (sewage) first enters and from which the solids are removed as raw sludge.

Primary Sludge. Sludge from primary clarifiers.

Primary Treatment. The removal of material that floats or will settle in sewage by using screens to catch the floating objects and tanks for the heavy matter to settle in. The first major treatment and sometimes the only treatment in a waste-treatment works, usually sedimentation and/or flocculation and digestion. The removal of a moderate percentage of suspended matter but little or no colloidal or dissolved matter. May effect the removal of 30 to 35 percent or more BOD.

Process Waste Water. Any water which, during manufacturing or processing, comes into direct contact with or results from the production or use of any raw material, intermediate product, finished product, by-product, or waste product.

Process Water. Any water (solid, liquid or vapor) which, during the manufacturing process, comes into direct contact with any raw material, intermediate product, by-product, waste product, or finished product.

Putrefaction. Biological decomposition of organic matter accompanied by the production of foul-smelling products associated with anaerobic conditions.

Pyrolysis. The high temperature decomposition of complex molecules that occurs in the presence of an inert atmosphere (no oxygen present to support combustion).

Quench. A liquid used for cooling purposes.

Raw Waste Load (RWL). The quantity (kg) of pollutant being discharged in a plant's wastewater. measured in terms of some common denominator (i.e., kkg of production or m^2 of floor area).

Receiving Waters. Rivers, lakes, oceans or other courses that receive treated or untreated wastewaters.

Recirculation. The refiltration of either all or a portion of the effluent in a high-rate trickling filter for the purpose of maintaining a uniform high rate through the filter. (2) The return of effluent to the incoming flow to reduce its strength.

Reduction. A process in which an atom (or group of atoms) gain electrons. Such a process always requires the input of energy.

Refractory Organics. Organic materials that are only partially degraded or entirely nonbiodegradable in biological waste treatment processes. Refractory organics include detergents, pesticides, color- and odor-causing agents, tannins, lignins, ethers, olefins, alcohols, amines, aldehydes, ketones, etc.

Residual Chlorine. The amount of chlorine left in the treated water that is available to oxidize contaminants if they enter the stream. It is usually in the form of hypochlorous acid of hypochlorite ion or of one of the chloramines. Hypochlorite concentration alone is called "free chlorine residual" while together with the chloramine concentration their sum is called "combined chlorine residual."

Respiration. Biological oxidation within a life form; the most likely energy source for animals (the reverse of photosynthesis).

Retention Time. Volume of the vessel divided by the flow rate through the vessel.

Retort. A vessel, commonly a glass bulb with a long neck bent downward, used for distilling or decomposing substances by heat.

Reverse Osmosis. The process in which a solution is pressurized to a degree greater than the osmotic pressure of the solvent, causing it to pass through a membrane.

Salt. A compound made up of the positive ion of a base and the negative ion of an acid.

Sanitary Landfill. A sanitary landfill is a land disposal site employing an engineered method of disposing of solid wastes on land in a manner that minimizes environmental hazards by spreading the wastes in thin layers, compacting the solid wastes to the smallest practical volume, and applying cover material at the end of each operating day. There are two basic sanitary landfill methods; trench fill and area or ramp fill. The method chosen is dependent on many factors such as drainage and type of soil at the proposed landfill site.

Sanitary Sewers. In a separate system, pipes in a city that carry only domestic wastewater. The storm water runoff is handled by a separate system of pipes.

Screening. The removal of relatively coarse, floating and suspended solids by straining through racks or screens.

Secondary Treatment. The second step in most waste treatment systems in which bacteria consume the organic part of the wastes. This is accomplished by bringing the sewage and bacteria together either in trickling filters or in the activated sludge process.

Sedimentation, Final. The settling of partly settled, flocculated or oxidized sewage in a final tank. (The term settling is preferred).

Sedimentation, Plain. The sedimentation of suspended matter in a liquid unaided by chemicals or other special means and without any provision for the decomposition of the deposited solids in contact with the sewage. (The term plain settling is preferred).

Seed. To introduce microorganisms into a culture medium.

Settleable Solids. Suspended solids which will settle out of a liquid waste in a given period of time.

Settling Velocity. The terminal rate of fall of a particle through a fluid as induced by gravity or other external forces.

Sewage, Raw. Untreated sewage.

Sewage, Storm. The liquid flowing in sewers during or following a period of heavy rainfall and resulting therefrom.

Sewerage. A comprehensive term which includes facilities for collecting, pumping, treating and disposing of sewage; the sewerage system and the sewage treatment works.

SIC Codes. Standard Industrial Classification. Numbers used by the U.S. Department of Commerce to denote segments of industry.

Silt. Particles with a size distribution of 0.05mm-0.002mm (2.0mm). Silt is high in quartz and feldspar.

Skimming. Removing floating solids (scum).

Sludge, Activated. Sludge floc produced in raw or settled sewage by the growth of zoogleal bacteria and other organisms in the presence of dissolved oxygen and accumulated in sufficient concentration by returning the floc previously formed.

Sludge, Age. The ratio of the weight of volatile solids in the digester to the weight of volatile solids added per day. There is a maximum sludge age beyond which no significant reduction in the concentration of volatile solids will occur.

Sludge, Digested. Sludge digested under anaerobic conditions until the volatile content has been reduced, usually by approximately 50 percent or more.

Solution. A homogeneous mixture of two or more substances of dissimilar molecular structure. In a solution, there is a dissolving medium-solvent and a dissolved substance-solute.

Solvent. A liquid which reacts with a material, bringing it into solution.

Solvent Extraction. A mixture of two components is treated by a solvent that preferentially dissolves one or more of the components in the mixture. The solvent in the extract leaving the extractor is usually recovered and reused.

Sparger. An air diffuser designed to give large bubbles, used singly or in combination with mechanical aeration devices.

Sparging. Heating a liquid by means of live steam entering through a perforated or nozzled pipe (used, for example, to coagulate blood solids in meat processing).

Standard Deviation. The square root of the variance which describes the variability within the sampling data on the basis of the deviation of individual sample values from the mean.

Standard Raw Waste Load (SRWL). The raw waste load which characterizes a specific subcategory. This is generally computed by averaging the plant raw waste loads within a subcategory.

Steam Distillation. Fractionation in which steam introduced as one of the vapors or in which steam is injected to provide the heat of the system.

Sterilization. The complete destuction of all living organisms in or on a medium; heat to 121°C at 5 psig for 15 minutes.

Still Bottom. The residue remaining after distillation of a material. Varies from a watery slurry to a thick tar which may turn hard when cool.

Stillwell. A pipe, chamber, or compartment with comparatively small inlet or inlets communicating with a main body of water. Its purpose is to dampen waves or surges while permitting the water level within the well to rise and fall with the major fluctuations of the main body of water. It is used with water-measuring devices to improve accuracy of measurement.

Stoichiometric. Characterized by being a proportion of substances exactly right for a specific chemical reaction with no excess of any reactant or product.

Stripper. A device in which relatively volatile components are removed from a mixture by distillation or by passage of steam through the mixture.

Substrate. (1) Reactant portion of any biochemical reaction, material transformed into a product. (2) Any substance used as a nutrient by a microorganism. (3) The liquor in which activated sludge or other material is kept in suspension.

Sulfate. The final decomposition product of organic sulfur compounds.

Supernatant. Floating above or on the surface.

Surge tank. A tank for absorbing and dampening the wavelike motion of a volume of liquid; an in-process storage tank that acts as a flow buffer between process tanks.

Suspended Solids. The wastes that will not sink or settle in sewage. The quantity of material deposited on a filter when a liquid is drawn through a Gooch crucible.

Synergistic. An effect which is more than the sum of the individual contributors.

Synergistic Effect. The simultaneous action of separate agents which, together, have greater total effect than the sum of their individual effects.

Tablet. A small, disc-like mass of medicinal powder used as a dosage form for administering medicine.

Tertiary Treatment. A process to remove practically all solids and organic matter from wastewater. Granular activated carbon filtration is a tertiary treatment process. Phosphate removal by chemical coagulation is also regarded as a step in tertiary treatment.

Thermal Oxidation. The wet combustion of organic materials through the application of heat in the presence of oxygen.

TKN (Total Kjeldahl Nitrogen). Includes ammonia and organic nitrogen but does not include nitrite and nitrate nitrogen. The sum of free nitrogen and organic nitrogen in a sample.

TLm. The concentration that kills 50% of the test organisms within a specified time span, usually in 96 hours or less. Most of the available toxicity data are reported as the median tolerance limit (TLm). This system of reporting has been misapplied by some who have erroneously inferred that a TLm value is a safe value, whereas it is merely the level at which half of the test organisms are killed. In many cases, the differences are great between TLm concentrations and concentrations that are low enough to permit reproduction and growth. LC50 has the same numerical value as TLm.

Total Organic Carbon (TOC). A measure of the amount of carbon in a sample originating from organic matter only. The test is run by burning the sample and measuring the carbon dioxide produced.

Total Solids. The total amount of solids in a wastewater both in solution and suspension.

Total Volatile Solids (TVS). The quantity of residue lost after the ignition of total solids.

Transport Water. Water used to carry insoluble solids.

Trickling Filter. A bed of rocks or stones. The sewage is trickled over the bed so that bacteria can break down the organic wastes. The bacteria collect on the stones through repeated use of the filter.

Trypsinize. To treat with trypsin, a proteolytic enzyme of the pancreatic juice, capable of converting proteins into peptone.

Turbidity. A measure of the amount of solids in suspension. The units of measurement are parts per million (ppm) of suspended solids or Jackson Candle Units. The Jackson Candle Unit (JCU) is defined as the turbidity resulting from 1 ppm of fuller's earth (and inert mineral) suspended in water. The relationship between ppm and JCU depends on particle size, color, index of refraction; the correlation between the two is generally not possible. Turbidity instruments utilize a light beam projected into the sample fluid to effect a measurement. The light beam is scattered by solids in suspension and the degree of light attenuation or the amount of scattered light can be related to turbidity. The light scattered is called the Tyndall effect and the scattered light the Tyndall light. An expression of the optical property of a sample which causes light to be scattered and absorbed rather than transmitted in straight lines through the sample.

Viruses. (1) An obligate intracellular parasitic microorganism smaller than bacteria. Most can pass through filters that retain bacteria. (2) The smallest (10-300 um in diameter) form capable of producing infection and diseases in man or other large species. Occurring in a variety of shapes, viruses consist of a nucleic acid core surrounded by an outer shell (capsid) which consists of numerous protein subunits (capsomeres). Some of the larger viruses contain additional chemical substances. The true viruses are insensitive to antibictics. They multiply only in living cells where they are assembled as complex macromolecules utilizing the cells' biochemical systems. They do not multiply by division as do intracellular bacteria.

Volatile Suspended Solids (VSS). The quantity of suspended solids lost after the ignition of total suspended solids.

Waste Treatment Plant. A series of tanks, screens, filters, pumps and other equipment by which pollutants are removed from water.

Wasterwater. Process water contaminated to such an extent it is not reusable in the process without repurification.

Water Quality Criteria. Those specific values of water quality associated with an identified beneficial use of the water under consideration.

Weir. A flow measuring device consisting of a barrier across an open channel, causing the liquid to flow over its crest. The height of the liquid above the crest varies with the volume of liquid flow.

Wet Air Pollution Control. The technique of air pollution abatement utilizing water as an absorptive media.

Wet Oxidation. The direct oxidation of organic matter in wastewater liquids in the presence of air under heat and pressure; generally applied to organic matter oxidation in sludge.

Zeolite. Various natural or synthesized silicates used in water softening and as absorbents.

Zooplankton. (1) The animal portion of the plankton. (2) Collective term for the nonphotosynthetic organisms present in plankton; contrasts with phytoplankton.

SECTION XVII

ABBREVIATIONS AND SYMBOLS

A.C.	activated carbon
ac.ft.	acre foot
Ag.	silver
atm.	atmosphere
ave.	average
B.	Boron
Ba.	Barium
bbl.	barrel
BOD_5	biochemical oxygen demand, five day
Btu	British thermal unit
C	centigrade degrees
C.A.	carbon adsorption
cal.	calorie
cc	cubic centimeter
cfm	cubic foot per minute
cfs	cubic foot per second
Cl.	chloride
cm	centimeter
CN	cyanide
COD	chemical oxygen demand
conc.	concentration
cu m	cubic meter
db	decibels
deg	degree
DO	dissolved oxygen
E. Coli	Escherichia coliform bacteria
Eq.	equation
F	Fahrenheit degrees
Fig.	figure
F/M	food to microorganism ratio (lbs BOD/lbs MLSS)
fpm	foot per minute
fps	foot per second
ft	foot
g	gram
gal	gallon
gpd	gallon per day
gpm	gallon per minute
Hg	mercury
hp	horsepower
hp-hr	horsepower-hour
hr	hour
in	inch
kg	kilogram
kw	kilowatt
kwhr	kilowatthour

L(l)	liter
L/kkg	liters per 1000 kilograms
lb	pound
m	meter
M	thousand
me	milliequivalent
mg	milligram
mgd	million gallons daily
min	minute
ml	milliliter
MLSS	mixed-liquor suspended solids
MSVSS	mixed-liquor volatile suspended solids
mm	millimeter
MM	million
mole	gram-molecular weight
mph	mile per hour
MPN	most probable number
mu	millimicron
NO_3	nitrate
NH_3-N	ammonia nitrogen
O_2	oxygen
PO_4	phosphate
p.	page
pH	potential hydrogen or hydrogen-ion index (negative logrithm of the hydrogen-ion concentration)
POTW	Publicly Owned Treatment Works
pp.	pages
ppb	parts per billion
ppm	parts per million
psf	pound per square foot
psi	pound per square inch
R.O.	reverse osmosis
rpm	revolution per minute
R.W.L.	raw waste load
sec	second
Sec.	Section
S.I.C.	Standard Industrial Classification
SO_x	sulfates
sq	square
sq.ft.	square foot
SS	suspended solids
stp	standard temperature and pressure
SRWL	standard raw waste load
TDS	total dissolved solids
TKN	total Kjeldahl nitrogen
TLm	median tolerance limit
TOC	total organic carbon
TOD	total oxygen demand
TSS	total suspended solids
u	micron
ug	microgram
vol	volume
wt	weight
yd	yard

TABLE XVIII

METRIC TABLE

CONVERSION TABLE

MULTIPLY (ENGLISH UNITS)		by	TO OBTAIN (METRIC UNITS)	
ENGLISH UNIT	ABBREVIATION	CONVERSION	ABBREVIATION	METRIC UNIT
acre	ac	0.405	ha	hectares
acre-feet	ac ft	1233.5	cu m	cubic meters
British Thermal Unit	BTU	0.252	kg cal	kilogram-calories
British Thermal Unit/Pound	BTU/lb	0.555	kg cal/kg	kilogram calories/kilogram
cubic feet/minute	cfm	0.028	cu m/min	cubic meters/minute
cubic feet/second	cfs	1.7	cu m/min	cubic meters/minute
cubic feet	cu ft	0.028	cu m	cubic meters
cubic feet	cu ft	28.32	l	liters
cubic inches	cu in	16.39	cu cm	cubic centimeters
degree Fahrenheit	°F	0.555 (°F-32)*	°C	degree Centigrade
feet	ft	0.3048	m	meters
gallon	gal	3.785	l	liters
gallon/minute	gpm	0.0631	l/sec	liters/second
horsepower	hp	0.7457	kw	killowatts
inches	in	2.54	cm	centimeters
inches of mercury	in Hg	0.03342	atm	atmospheres
pounds	lb	0.454	kg	kilograms
million gallons/day	mgd	3,785	cu m/day	cubic meters/day
mile	mi	1.609	km	kilometer
pound/square inch (gauge)	psig	(0.06805 psig +1)*	atm	atmospheres (absolute)
square feet	sq ft	0.0929	sq m	square meters
square inches	sq in	6.452	sq cm	square centimeters
ton (short)	ton	0.907	kkg	metric ton (1000 kilograms)
yard	yd	0.9144	m	meter

*Actual conversion, not a multiplier