(Sec. 7805 of the Internal Revenue Code of 1954 (68A Stat. 917; 26 U.S.C. 7805).)

DONALD C. ALEXANDER,
Commissioner of Internal Revenue.

Approved:

WILLIAM M. GOLDSTEIN,
Deputy Assistant Secretary of the Treasury.

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Title 29—Labor

CHAPTER XII—FEDERAL MEDIATION AND CONCILIATION SERVICE

PART 1404—ARBITRATION SERVICES

Revision

On April 22, 1976, a document was published in the FEDERAL REGISTER (41 FR 16831) proposing to revise Chapter XII of Title 29 of the Code of Federal Regulations, by amending Part 1404 thereof. Part 1404 contains the policies and procedures of the Federal Mediation and Conciliation Service in its Arbitration Services program. The proposed revision was intended to redefine the policy of the FMCS Arbitration Services program, the standards of eligibility of arbitrators for admission to and retention on the roster, the procedures for arbitration services and proceedings, and the procedure for administrative action regarding arbitrators on the roster.

Interested persons were invited to submit comments, data, or argument on the proposed amendments and numerous comments were received. All comments with respect to the proposed amendment were given due consideration by the agency.

In addition to language changes made for clarification, as a result of the comments received and after full consideration, the following changes in the revised rules are made:

The section of the proposed regulations most frequently commented upon was proposed § 1404.2, *Standards for Admission to and Retention on the Roster.* These standards applied to both applicants to and members of the roster. As a result of the analysis of the comments, it was felt that these standards could be more readily understood and applied if they were divided into three subheadings. Accordingly § 1402.2 was restructured as follows: (a) *General Criteria,* applying to both applicants and arbitrators on the roster; (b) *Special Criteria for Arbitrator* Applicants; and (c) *Special Criteria for Arbitrators.*

The most critical comments received concerned proposed § 1404.2(b), which set forth the standard of actual arbitration experience as the preferred experience for arbitrator applicants, and set forth the possibility that others "may" be considered in conjunction with training programs. The comments were critical of the restrictive nature of the actual arbitration experience standard and the apparent exclusion of individuals experienced in the arbitration field as advocates but not arbitrators and also applicants who are acceptable neutrals but not experienced in labor relations or arbitration matters. In addition, some of the comments were critical of the lack of provision in the regulations to allow for adequate training and development of applicants to acquire the necessary experience.

It was concluded that the proposed § 1404.2 did create the impression that significant actual arbitration experience was the only standard for admission, to the exclusion of training and development, and that clarification of the training standard was in order. In addition it was felt that the definition of advocacy contained in proposed § 1404.2(e) contributed to this impression by appearing to exclude former advocates as applicants.

The advocacy standard with respect to applicants was clarified in § 1404.2(b)(3) to be applicable only to those individuals who are advocates at the time of their application, so that retired advocates are clearly eligible for consideration. For those applicants lacking sufficient direct arbitration experience, the provisions for training were amplified in § 1404.2(b)(2) to demonstrate the means by which an applicant may gain the necessary arbitration experience. It is intended that the necessity for and evaluation of such training be applied on an individual basis, depending on the individual's background, so as to allow for a flexible attainment of the ultimate standard of actual arbitration experience. The Service considers it essential that the test of actual arbitration experience be retained so that it can be assured that the persons it admits to the roster are capable of functioning and being selected by the parties as arbitrators. The Service considers that the inconvenience suffered by individuals with substantial qualifications but lacking actual arbitration experience in undergoing a minimum of training is more than offset by the Service's obligation to admit, retain and refer qualified arbitrators to the parties.

A few comments were made that proposed § 1404.2(b) was too restrictive in requiring all applicants to have experience in many industries and bargaining units. After deliberation, it was concluded that such a qualification was not necessary and it has been omitted from § 1404.2(b).

Other comments pertaining to proposed § 1404.2 dealt with the exclusion of advocates from admission to or retention on the roster. The vast majority of comments on the matter favored the exclusion of applicants who are advocates. The comments received generally indicated the view that such persons are unacceptable to the parties. Other comments suggested that selection of members on the roster should be the underlying basis for determining the composition of the roster. As a result of the discussion and analysis of the comments, it was felt that due to the relationship between advocacy and selection, the prohibition of advocates should be handled differently for applicants and arbitrators currently on the roster. It has been the experience of the Service that an applicant who is an advocate will ordinarily prove to be unacceptable to the parties.

Section 1404.2(b)(3) provides that an applicant who is an advocate is ineligible for admission unless he demonstrates a "very high acceptability." Section 1404.2(c) requires a roster member to list his advocacy on the biographical sketch to be submitted to the parties and provides, as a test of his acceptability, that he possess a "sufficient rate of selection" by the parties. It was concluded that the criteria for the acceptability/selection standard as an exception to the prohibition of advocacy ought to be treated differently for applicants and those currently on the roster because:

(a) By reason of the requirement that arbitrators disclose their advocacy to the parties in advance of their selection, a substantial part of the objection to advocacy is answered, and the focus will then shift to rate of selection. In the meantime an arbitrator on the roster is afforded the opportunity to determine whether or not to continue such advocacy, particularly as it may affect the rate of selection.

(b) The record of selection of such advocates on the roster is capable of demonstration by the Service's records, whereas the record of an applicant's acceptability/selection is based upon by information submitted by the applicant.

In addition, § 1404.2(c) is designed to identify those individuals who are not being utilized by the parties and who may create an unnecessary delay and inconvenience in including them on panels for referral to the parties. Consequently, the standard for removal of persons on the roster based on lack of selection, previously proposed in § 1404.2(a) in a cursory manner, was restated in § 1404.2(c)(3), and is intended to be applied to all members on the roster, whether advocates or persons who, for a lack of experience or other reasons, are not selected by the parties.

In addition to the comments regarding advocacy, it was also suggested that the reference to an actual or apparent conflict of interest contained in proposed § 1404.2(e)(3) as a standard for admission or retention was vague and uncertain. It was felt that retention of conflict of interest language was necessary to apply to unforeseen situations which might arise on a case-by-case basis. It was also felt that examples of a conflict of interest should be set forth in an effort to identify the types of situations where a conflict may appear, depending on the facts of the case. This was accomplished in § 1404.2(a)(8) which sets forth advocacy or employment with labor or management as examples of possible conflicts of interest. It is intended that this language be applicable independent of the prohibition of advocacy for applicants or necessity to disclose advocacy for those on the roster, and will be applied on a case-by-case basis, depending on the relationship between the arbitrator and the parties to the case in question.

A comment was made that the certification of an applicant or an arbitrator contained in proposed § 1404.2(a)(k)

should be for a time certain to insure examination by the Service of the arbitrator's continued qualifications and compliance with these regulations. It was concluded that the suggestion was well made and is reflected in § 1404.2(a)(7) by certification periods of two and three years, respectively, for applicants and those on the roster.

Comments were made that the 30 day period of time, contained in proposed § 1404.15(a) wherein an arbitrator should issue an award after closing the record, was too restrictive. It was also commented that the failure of an arbitrator to render timely awards should be a basis for their removal from the roster. It was concluded in § 1404.15(a) to extend the period of time ordinarily expected for rendition of an award to 60 days, absent agreement of the parties. In view of § 1404.2(a)(2), which reserves the right for the Service to remove arbitrators for failure to comply with the regulations, it was not felt that specific mention of disciplinary authority was necessary to be specified in § 1404.15(a). Nevertheless a new sentence was added to impress upon arbitrators that discipline is possible for the failure to render timely awards.

Several comments suggested that the policy of the Service reflected in proposed § 1404.15(d) not to release awards for publication without the consent of both parties was erroneous and that the Service should publish all awards. It was concluded that the Service has no basis to publish awards absent the consent of both parties and, that further, the Service lacks sufficient staffing and financial resources to engage in this endeavor. Consequently, no change was made.

Comments were made suggesting that proposed § 1404.16(b), allowing the arbitrator to charge for cancellation of hearing dates, etc., be altered. It was suggested that specific time frames be established whereby the faliure to give timely notice of cancellation, etc., would be a prerequisite to the arbitrator's charging a cancellation fee. It was also suggested that each arbitrator establish in the biographical sketch the conditions under which such a cancellation charge will be made. It was also commented that the administrative charges specified in § 140.16(d) for unusual amounts of time for handling administrative matters was too restrictive upon an arbitrator who is entitled to be reasonably compensated. In the discussion and analysis of these comments, it was concluded that the suggestion for inclusion of charges with the biographical sketch was warranted. It was felt that the process of selection and the relationship of the Service with the arbitrator and the parties is better served by selection based on disclosure of information about the arbitrator's fee schedule rather than by the Service setting a hard and fast rule and becoming the enforcer of such rules. Inasmuch as disclosure of arbitrator charges prior to selection, is now required, the proposed specification of the appropriateness of charges for cancellation fees and fees for interest arbitration cases, in addition to the per diem fee listed in proposed § 1404.16(a), was not considered necessary. Consequently, proposed § 1404.16(a) has been expanded to require the listing of all fees on the arbitrator's biographical sketch and proposed § 1404.16 (b) and (c) have been eliminated in the final rules. However, proposed § 1404.16(d), that allowed for administrative charges for unusual amounts of time and expenses, was retained and renumbered as § 1404.16(b). It was concluded that these charges are usually unforeseeable by the arbitrator before or at the time of his selection, and are not capable of prior disclosure.

Two subsections were added. Section 1404.16(c) makes it clear that unless the charges are listed on or attached to the biographical sketch as required by § 1404.16(a), or are unusual charges covered by § 1404.16(b), any additional charges by the arbitrator are not warranted unless he notifies the parties of such charges immediately after appointment and obtains the consent of the parties.

Section 1404.16(d) was added to reflect the fact that the Service will not act as a collection agency for arbitrators nor become a forum wherein claims by the parties as to the appropriateness of the charges may be litigated. The only interest of the Service is to ensure that arbitrators on its roster are conforming to the fee policies expressed in the regulations.

Regarding proposed Subpart C, *Procedure for Administrative Action*, an extremely limited number of comments were received. After careful consideration and review, it was concluded that under the prior regulations, which did not contain such a formal procedure, the Service was able to adequately address alleged violations of regulations and standards. In addition, the clarifications and modifications encompassed in these regulations provide adequate notice to all applicants and members of our roster as to the standards applicable for admission and retention. For these reasons, along with continuing budgetary constraints, it has been decided that Subpart C will not be implemented at this time. The Service will, however, continue to administer these regulations and all related policies in a manner that will ensure fair and equal treatment to all current and future applicants to and members of the roster of arbitrators.

Accordingly, 29 CFR Part 1404 is revised as set forth below.

Effective date: This regulation shall become effective on November 17, 1976.

Adopted by the Federal Mediation and Conciliation Service at its office in Washington, D.C., on the 11th day of November 1976.

JAMES F. SCEARCE,
National Director.

29 CFR Part 1404 is revised as set forth below:

Subpart A—General Policy and Standards of Eligibility

Sec.
1404.1 Arbitration.
1404.2 Standards for admission and retention on the roster.

Subpart B—Procedures for Arbitration Services

1404.10 Procedures for requesting arbitration panels.
1404.11 Arbitrability.
1404.12 Nominations of arbitrators.
1404.13 Selection and appointment of arbitrators.
1404.14 Status of arbitrator and conduct of hearings.
1404.15 Decision and award.
1404.16 Fees and charges of arbitrators.

AUTHORITY: The provisions of this Part 1404 issued under sec. 202, 61 Stat. 153, as amended; 29 U.S.C. 172. Interpret or apply sec. 3, 80 Stat. 250, sec. 203, 61 Stat. 153; 5 U.S.C. 552, 29 U.S.C. 173.

Subpart A—General Policy and Standards of Eligibility

§ 1404.1 Arbitration.

(a) The labor policy of the U.S. Government is designed to foster and promote free collective bargaining. Voluntary arbitration is encouraged by public policy and is, in fact, widely utilized by the parties to resolve disputes involving the interpretation or application of collective bargaining agreements. Also, in appropriate cases, voluntary arbitration and factfinding of interest disputes are features of free collective bargaining and are alternatives to economic strife in settling the terms of a collective bargaining agreement. The parties assume broad responsibilities for the success of this private system of dispute resolution they have chosen.

(b) The Federal Mediation and Conciliation Service is sometimes referred to herein as FMCS or the Service and the Office of Arbitration Services of the Service is sometimes referred to herein as OAS. The Service has established the OAS to implement the provisions of this part.

§ 1404.2 Standards for admission and retention on the roster.

(a) *General Criteria.* (1) It is the policy of the Service to admit and retain qualified, competent, acceptable and ethical arbitrators on its roster. Consequently, in addition to requiring compliance with the rules and regulations set out herein by the Service and such guidelines and procedures as may be issued by the OAS, each arbitrator shall conform to the ethical standards and procedures set forth in the Code of Professional Responsibility for Arbitrators of Labor-Management Disputes approved by the Joint Steering Committee of the National Academy of Arbitrators (composed of representatives from the Academy, the American Arbitration Association, and the Service) in November 1974 and published in April 1975, incorporated by reference herein.

(2) The Service reserves the right to remove arbitrators from the roster or to

take other appropriate action where the Service finds that an arbitrator does not adhere to these regulations and related policies, or does not meet its standards as set forth herein.

(3) All applicants and arbitrators on the roster must be able to demonstrate acceptable ability in analysis, recommendations, and decision writing. Such persons must also be able to conduct a due process hearing in an orderly manner, be physically and mentally equipped to withstand the tensions of an adversary proceeding, and be able to speak and write in a clear and concise manner.

(4) All applicants and arbitrators on the roster shall be able to conduct fair and impartial proceedings and render impartial awards.

(5) The Service requires that applicants and those on the roster keep current with developments that are relevant to arbitration practice.

(6) Inquiries relative to the qualifications of applicants to and those on the roster may be made of arbitrators or FMCS personnel familiar with the applicant, and union and management arbitration practitioners.

(7) Applicants who qualify under the criteria for admission to the FMCS roster of arbitrators shall be certified by the National Director of FMCS for a period of two years. Arbitrators currently on the roster, following an evaluation of their continuing compliance with the standards contained herein, shall be certified for a period of three years. The entire roster of arbitrators shall periodically be reviewed for purposes of determining continued compliance with the standards contained herein and continued retention on the roster.

(8) In deciding which persons will not be admitted to or retained on the roster the Service may further consider whether a person has an actual or apparent bias or an actual or apparent conflict of interest. Examples of such bias or conflict of interest are:

(i) Individuals serving as advocates or representatives of labor or management within the meaning of § 1404.2(b)(3).

(ii) An officer or employee of a corporation or labor organization who could be identified with the institution even though not functioning in a labor relations capacity.

(b) *Special criteria for arbitrator applicants.* (1) Applicants for inclusion on the roster should be able to demonstrate experience, competence, and acceptability in a decision-making role in the resolution of labor relations disputes. Preferred third party experience is actual arbitration experience in labor-management matters. Such experience in labor-management matters will be weighted, considering the frequency of such experience, its complexity, the variety of issues wherein such experience is gained, and the needs of the parties in a given geographic area.

(2) Applicants who do not possess the above experience qualifications as arbitrators will be considered who have considerable experience in relevant positions in collective bargaining and have shown professional growth and stability and who participate in acceptable orientation and training programs for arbitrators. Such training programs may consist of:

(i) Formal training programs conducted by a university, local bar association, or joint labor-management association.

(ii) Informal training programs consisting of a period of internship with an arbitrator on the FMCS roster with specific advance approval of the Service. The requirements will vary depending on the needs of the parties in a given area and the relative experience of an applicant in labor relations generally and the experience in the resolution of labor relations disputes. The Service will look with favor on those internships which require attendance at hearings with the instructing arbitrator, researching the issues involved, and furnishing draft decisions to the arbitrator and/or Service, and the requirement that the applicant be selected, conduct hearings, and issue awards without regard to such internship. In evaluating the experience of applicants as arbitrator, the Service will consider evaluations of the applicant's performance by the parties to a given case.

(iii) In appropriate situations, other types of training or internship.

(3) Applicants, who at the time of their application to the roster, are employees of, advocates for, or who represent labor or management shall not be eligible for admission to the roster except as noted herein. An advocate, or representative or employee is defined as one who represents management or labor in matters of labor relations, including but not limited to the subjects of collective bargaining, unfair labor practices, equal employment opportunity and other areas generally recognized as constituting labor relations. Applicants who are employees of, advocates for, and representatives of labor or management may be considered for appointment to the roster if, in the opinion of the Service, they have demonstrated a prior record of very high acceptability as an arbitrator by both labor and management and their inclusion will not preclude their possibility of selection by parties to a dispute.

(c) *Special criteria for arbitrators.* (1) The arbitrators on the roster shall execute and return all documents, forms, and reports required by the Service. In addition, they shall keep the Service informed of changes of address, telephone numbers, occupation, availability, and of any business or other connection or relationship which involves labor-management relations.

(2) An arbitrator must keep the Service apprised of his status as an employee of, advocate for, or representative of labor or management within the definition contained in § 1404.2(b)(3). Such information will be so noted on the arbitrator's biographical sketch which will be submitted to the parties in accordance with § 1404.12.

(3) Arbitrators on the roster must be acceptable to the parties and be able to contribute to the expeditious and competent resolution of arbitration disputes. Accordingly, the Service may remove arbitrators from the roster whose record does not reflect a sufficient rate of selection as determined by the record of referrals to and selection by the parties following requests to FMCS for submission of panels.

Subpart B—Procedures for Arbitration Services

§ 1404.10 Procedures for requesting arbitration panels.

The Office of Arbitration Services has been delegated the responsibility for administering all requests for arbitration services under these regulations.

(a) The Service will refer a panel of arbitrators to the parties upon request. The Service prefers to act upon a joint request which should be addressed to the Federal Mediation and Conciliation Service, Washington, D.C. 20427, Attention: Office of Arbitration Services. In the event that the request is made by only one party, the Service will submit a panel; however, any submission of a panel should not be construed as anything more than compliance with a request and does not necessarily reflect the contractual requirements of the parties.

(b) The parties are urged to use the Request for Arbitration Panel form (R-43) which has been prepared by the Service and is available in quantity at all FMCS regional offices and field stations or upon request to the Office of Arbitration Services, 2100 K Street, Washington, D.C. 20427. The form R-43 is reproduced herein for purposes of identification:

Sep 1975

FEDERAL MEDIATION AND CONCILIATION SERVICE
WASHINGTON, D.C. 20427

OMB NO. 23-R0007

REQUEST FOR ARBITRATION PANEL

To: Director, Arbitration Services
Federal Mediation and Conciliation Service
Washington, D.C. 20427

Date _____

1. (For Company)

Name of Company _____

Name and Address of Representative to Receive Panel _____ (NAME)
_____ (STREET)
_____ (CITY, STATE, ZIP)

Telephone (include area code) _____

2. (For Union)

Name of Union and Local No. _____

Name and Address of Representative to Receive Panel _____ (NAME)
_____ (STREET)
_____ (CITY, STATE, ZIP)

Telephone (include area code) _____

3. Site of Dispute _____ (CITY, STATE, ZIP)

4. Type of Issue _____ (DISCHARGE, HOLIDAY PAY, SICK LEAVE, ETC.)

5. A panel of seven (7) names is usually provided; if you desire a different number, please indicate _____

6. Type of Industry

- ☐ Manufacturing
- ☐ Construction
- ☐ Mining, Agriculture and Finance
- ☐ Federal Government
- ☐ State Government
- ☐ Local Government
- ☐ Public Utilities, Communications, Transportation (including trucking)
- ☐ Retail, Wholesale and Service Industries
- ☐ Other (Specify) _____

7. Special Requirements _____
(SPECIAL ARBITRATOR QUALIFICATIONS, TIME LIMITATIONS ON HEARING OR DECISION, GEOGRAPHICAL RESTRICTIONS, ETC.)

8. Signatures

_____ (COMPANY)

_____ (UNION)

Although the FMCS prefers to act upon a joint request of the parties, a submission will be made based on the request of a single party. However, any submission of a panel should not be construed as anything more than compliance with a request and does not reflect on the substance or arbitrability of the issue in dispute.

Additional forms may be obtained from the Federal Mediation and Conciliation Service or any FMCS Regional Office. See list on reverse of Copy No. 3.

Copy No. 1, Original - To Federal Mediation and Conciliation Service

(c) A brief statement of the issues in dispute should accompany the request to enable the Service to submit the names of arbitrators qualified for the issues involved. The request should also include a current copy of the arbitration section of the collective bargaining agreement or stipulation to arbitrate.

(d) If form R-43 is not utilized, the parties may request a panel by letter which must include the names, addresses, and phone numbers of the parties, the location of the contemplated hearing, the issue in dispute, the number of names desired on the panel, the industry involved and any special qualifications of the panel or special requirement desired.

§ 1404.11 Arbitrability.

Where either party claims that a dispute is not subject to arbitration, the Service will not decide the merits of such claim. The submission of a panel should not be construed as anything more than compliance with a request for a panel.

§ 1404.12 Nominations of arbitrators.

(a) When the parties have been unable to agree on an arbitrator, the Service will submit to the parties the names of seven arbitrators unless the applicable collective bargaining agreement provides for a different number, or unless the parties themselves request a different number. Together with the submission of a panel of arbitrators, the Service will furnish a biographical sketch for each member of the panel. This sketch states the background, qualifications, experience, and per diem fee and other fees established by the arbitrator, such as cancellation, postponement rescheduling or administrative fees.

(b) When a panel is submitted, an FMCS control case number is assigned. All future communication between the parties and the Service should refer to the case number.

(c) In selecting names for inclusion on a panel, the Service considers many factors, but the desires of the parties are of foremost consideration. Special qualifications of arbitrators experienced in certain issues (e.g., incentive plans, equal employment opportunity, unfair labor practices, wage compensation, insurance, pensions), or industries (e.g., trucking, manufacturing, mining), or background (e.g., law, economics, engineering) may be identified for purposes of submitting panels to accommodate the parties.

(1) If at any time both parties request that a name or names be omitted from a panel, such name or names will be omitted, unless they are excessive in number or otherwise appear to lack careful consideration.

(2) If at any time both parties request that a name or names be included on a panel, such name or names will be included.

(3) If only one party requests that a name or names be omitted from a panel, or that specific individuals be added to the panel, such request shall not be honored.

(4) If the issue described in the request appears to require special technical experience or qualifications, arbitrators who possess such qualifications will, where possible, be included on the panel submitted to the parties.

(5) If one party requests that the panel be composed entirely of persons with specific qualifications, such request will be honored if the agreement so provides or the other party so agrees.

(6) In almost all cases, an arbitrator is chosen from one panel. However, if either party requests another panel, the Service shall comply with the request providing that an additional panel is permissible under the terms of the agreement or the other party so agrees. Requests for more than two panels must be accompanied by a statement of explanation and will be considered on a case-by-case basis.

(d) Subsequent settlement of disputes by agreement of the parties is not precluded by the submission of a panel or a selection of the arbitrator. In the event a dispute is settled by the parties after the initial request for a panel or after selection of the arbitrator, notice of such settlement shall be sent promptly to the arbitrator and to the Service. It is possible, that in accordance with § 1404.16, the arbitrator may be entitled to a fee, notwithstanding settlement following his or her selection.

§ 1404.13 Selection and appointment of arbitrators.

(a) The parties should notify the OAS of their selection of an arbitrator. The arbitrator, upon notification by the parties, shall notify the OAS of his selection and willingness to serve. Upon notification of the parties' selection of an arbitrator, the Service will make a formal appointment of the arbitrator.

(b) Where the contract is silent in the manner of selecting arbitrators, the parties may wish to consider one of the following two methods most commonly utilized by the parties for selection of an arbitrator from a panel:

(1) Each party alternately strikes a name from the submitted panel until one remains. The striking procedure is customarily completed at a joint meeting between the parties.

(2) Each party advises the Service of its order of preference by numbering each name on the panel and submitting the numbered list in writing to OAS. The name on the panel that has the lowest accumulated numerical number will be appointed.

(c) The Service will make a direct appointment of an arbitrator based upon a joint request or upon a unilateral request when the applicable collective bargaining agreement so authorizes.

(d) The arbitrator, upon appointment notification, is required to communicate with the parties immediately to arrange for preliminary matters, such as date and place of hearing.

§ 1404.14 Status of arbitrator and conduct of hearings.

(a) The arbitrators on the FMCS roster are not employees of the Federal Government; therefore, the Service does not investigate their security status. An arbitrator is selected by the parties and is retained by them and they must assume complete responsibility for the arbitrator's security status.

(b) After appointment, the legal relationship of an arbitrator is with the parties rather than the Service, although the Service does have a continuing interest in the proceedings and the performance of arbitrators maintained on its roster.

(c) All proceedings conducted by the arbitrator shall be in conformity with the contractual obligations specified by the parties. In addition, the arbitrator is expected to conduct all proceedings in conformity with § 1404.2(a)(1). The conduct of the arbitration proceeding is under the arbitrator's jurisdiction and control. The arbitrator's decision is to be based on the record in the proceedings. The arbitrator may, unless prohibited by law, proceed in the absence of any party who, after due notice, fails to be present or to obtain a postponement. The award, however, must be supported by evidence.

§ 1404.15 Decision and award.

(a) Arbitrators are encouraged to render awards not later than 60 days from the date of the closing of the record as determined by the arbitrator, unless otherwise agreed upon by the parties or specified by law. A failure to render an award within the 60 days required by FMCS may not affect the validity of such an award. However, it does reflect upon the performance of an arbitrator with regard to his continuing relationship with the FMCS roster.

(b) The parties should inform the OAS whenever a decision is unduly delayed. The arbitrator shall notify the OAS if and when the arbitrator (1) Cannot schedule, hear and determine issues promptly, and; (2) Learns a dispute has been settled by the parties prior to the decision.

(c) After an award has been submitted to the parties, the arbitrator is required to file a copy with the OAS. The arbitrator is further required to submit a Fee and Award Statement, form R–19, showing a breakdown of the fee and expense charges so that the Service may be in a position to review conformance with its fee and expense reporting requirements. Filing both award and report within 15 days after rendering an award is required of all arbitrators.

(d) While the Service encourages the publication of arbitration awards, it is the policy of the Service not to release arbitration decisions for publication without the consent of both parties. Furthermore, the Service expects the arbitrators it has nominated or appointed not to give publicity to awards they issue if objected to by one of the parties.

§ 1404.16 Fees and charges of arbitrators.

(a) No administrative or filing fee is charged by the Service. The current policy of the Service permits each of its nominees or appointees to charge a per diem fee and other predetermined fees for services, the amount of which has been certified in advance to the Service. Each arbitrator's maximum per diem fee and other predetermined fees are set forth on a biographical sketch which is sent to the parties when panels are submitted, and are the controlling fees of the arbitrator selected. The arbitrator shall not change any fee to be noted on his or her biographical sketch without giving at least 30 days advance notice to the Service of the intention to do so.

(b) In cases involving unusual amounts of time and expenses relative to pre-hearing and post-hearing administration of a particular case, an administrative charge may be made.

(c) All charges other than those specified by § 1404.16(a) shall be divulged to and agreement obtained by the arbitrator with the parties immediately after appointment.

(d) The Service requests that it be notified of any arbitrator's deviation from the policies expressed herein. However, the Service will not attempt to make any resolution of any fee dispute or provide a forum to the parties for the Service making any determination of a fee dispute.

[FR Doc.76-33733 Filed 11-16-76;8:45 am]

Title 32—National Defense

CHAPTER VI—DEPARTMENT OF THE NAVY

PART 701—AVAILABILITY OF DEPARTMENT OF THE NAVY RECORDS AND PUBLICATION OF DEPARTMENT OF THE NAVY DOCUMENTS AFFECTING THE PUBLIC

Personal Privacy and Rights of Individuals Regarding Their Personal Records and Privacy Act Exemptions

On page 37568 of the FEDERAL REGISTER of August 26, 1975, notice of proposed rulemaking was published proposing to establish a Subpart F of Part 701 of 32 CFR entitled "Personal Privacy and Rights of Individuals Regarding Their Personal Records," and a Subpart G of Part 701 of 32 CFR entitled "Privacy Act Exemptions." On page 46060 of the FEDERAL REGISTER of October 3, 1975, there was published a modification to the proposed Subpart G of Part 701, which consisted of an additional Privacy Act exemption.

These two subparts reimplement within the Department of the Navy the provisions of the Privacy Act of 1974 (5 U.S.C. 552a), as implemented within the Department of Defense by Department of Defense Directive 5400.11 of August 4, 1975, entitled "Personal Privacy and Rights of Individuals Regarding Their Personal Records" [32 CFR Part 286a (40 FR 55518)]. Accordingly, these subparts are the codification of Secretary of the Navy Instruction 5211.5A (SECNA VINST 5211.5A) adopted on October 8, 1976.

Interested persons were afforded an opportunity to participate in the proposed rulemaking through the submission of written data, views, and arguments. All comments submitted with respect to the proposed rulemaking were given due consideration.

As a result of the comments received and further review of the proposed rules on the basis of the agency's operating experience under the Privacy Act of 1974, Subpart F of Part 701 of 32 CFR has been revised to improve the prescribed substantive guidance and operating procedures. Provisions have been added to provide for administrative review of initial denials of requests for notification and access, and accommodating the authority reserved by the Civil Service Commission in 5 CFR Part 297 to perform final administrative reviews of initial denials of requests for access or amendments of records in the government-wide systems under its cognizance. Provisions have been added to incorporate guidance received subsequent to August of 1975 from the Office of Management and Budget concerning implementation of the Privacy Act of 1974. Provisions effecting amendment procedures have been revised to provide that, among other things, (1) a request for amendment of a record may not be rejected nor may the requester be required to resubmit his request unless this would be essential for processing the request [§ 701.106(d)(2)(iv)], and (2) determinations and required action on initial requests for notification, access, or amendment of records shall be completed, if reasonably possible, within 30 working days of receipt by the cognizant office [§ 701.106(a)(6)(ii)]. Finally, revisions have been made to portions of Subpart G of Part 701 of 32 CFR to reorganize the provisions, and to reflect the changes made to Department of the Navy records systems as published in the FEDERAL REGISTER on July 26, 1976 (41 FR 30796).

These subparts to Part 701 of 32 CFR are established under the authority of

the Privacy Act of 1974, Pub. L. No. 93-579, 5 U.S.C. 552a.

Accordingly, Subparts F and G of Part 701 of 32 CFR are established as follows:

Subpart F—Personal Privacy and Rights of Individuals Regarding Their Personal Records

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AUTHORITY: Pub. L. No. 93-579, 5 U.S.C. 552a.

Subpart F—Personal Privacy and Rights of Individuals Regarding Their Personal Records

§ 701.100 Purpose.

This subpart implements the Privacy Act of 1974 (5 U.S.C. 552a) and Department of Defense Directive 5400.11, Personal Privacy and Rights of Individuals Regarding Their Personal Records (DOD Dir. 5400.11) by delineating and prescribing policies, conditions, and procedures for:

(a) Notifying an individual in response to his request if a Department of the Navy system of records named by the individual contains a record pertaining to him.

(b) Verifying the identity of an individual who requests his record, or information pertaining to him, before the record or information is made available.

(c) Granting access to an individual upon that individual's request for his record or for information pertaining to him.

(d) Reviewing a request from an individual concerning the amendment of any record or information pertaining to the individual, for making a determination on the request, and for an appeal of an initial adverse determination.

(e) Collection, safeguarding, maintenance, public notice, use, and dissemination of personal information.

(f) Disclosing personal information, and for exempting systems of records from the requirements of 5 U.S.C. 552a.

(g) Establishing rules of conduct for the guidance of Department of the Navy personnel, who will be subject to criminal penalties for non-compliance with the act.

§ 701.101 Scope and effect.

(a) *Applicability.* This subpart applies throughout the Department of the Navy, and to any contractor maintaining a system of records to accomplish a Department of the Navy purpose. Its provisions govern the collection, maintenance, use, and dissemination of personal information, and all requests from individuals who seek information on, access to, copies of, or amendment of records pertaining to themselves under the provisions of 5 U.S.C. 552a. Additionally, all requests received from individuals for copies or examination of records pertaining to themselves, and which are located in a system of records, as defined in § 701.105, will be processed in accordance with this subpart, even though the individuals specify that the requests are made under 5 U.S.C. 552 (Freedom of Information Act), SECNAVINST 5720.42B (32 CFR Part 701, subparts A–D), or other authority. This subpart does not apply to:

(1) Requests from individuals for access to records pertaining to themselves, but which are not included in a system of records, as defined in § 701.105. These requests will be processed in accordance with 32 CFR Part 701, Subparts A–D. Subsequent requests for amendment of such records, however, will normally be processed in accordance with this subpart.

(2) Requests for records pertaining to other individuals, where such individuals' consent is not provided. Such third party requests are governed by 32 CFR Part 701, Subparts A–D.

(3) Requests by the General Accounting Office for information or records pertaining to individuals, except with respect to the requirement for disclosure accountings as provided in paragraph (c) of § 701.107. Action on such requests is governed by, SECNAVINST 5741.2E.

(b) *Other directives.* Should any existing directive dealing with the disclosure of individual personal records conflict with this subpart, the provisions of this subpart shall take precedence.

§ 701.104 Policy, responsibilities, and authority.

(a) *Policy and general requirements.* (1) Subject to the conditions and directions in this subpart, it is the policy of the Department of the Navy to ensure that all personnel at all echelons of command or authority within the Department comply fully with the purposes and requirements of 5 U.S.C. 552a for preserving the privacy of information concerning individuals in departmental records. Stated generally, these purposes and requirements are:

(i) To permit individuals to know what records pertaining to them are collected, maintained, used, or disseminated in the Department, to have access to and have copies made of all or any portions of such records, and to obtain amendment of such records, when a discrepancy is noted;

(ii) To permit individuals to prevent records pertaining to them obtained by the Department for a particular purpose from being used or made available for another purpose without their consent;

(iii) To require the Department to collect, maintain, use, or disseminate records of identifiable personal information only for necessary and lawful purposes, and in a manner which ensures that the information is current and accurate for the intended uses;

(iv) To ensure that adequate safeguards are provided to prevent misuse of personal information in records; and

(v) To ensure that requests of individuals for notification, access, or amendments concerning their records are acted on as promptly as feasible, even though such requests may be minor in nature.

(2) In furtherance of the above policy, the Department of the Navy will maintain in its records only such information about an individual as is reasonably necessary to accomplish a purpose or mission required by statute or executive order of the President. In assessing need, consideration will be given to alternatives, such as: use of information not individually identifiable; use of sampling; selective collection of certain data for certain individuals, only. Additionally, consideration is to be given to the length of time information is needed, and the cost of maintaining the information compared to the risks and adverse consequences of not maintaining the information.

(3) No system of records, as defined in § 701.105(d) shall be maintained within the Department of the Navy unless it has been described or included in a records system notice published in the FEDERAL REGISTER, in accordance with § 701.108 of this Subpart.

(4) The Department of the Navy will not maintain any records describing how an individual exercises rights guaranteed by the first amendment, including religious and political beliefs, freedom of speech and press, and the right of assembly and to petition, unless they are:

(i) Expressly authorized by statute;

(ii) Authorized by the individual about whom the record is maintained;

(iii) Within the scope of an authorized law enforcement activity; or

(iv) For the maintenance of certain items of information relating to religious affiliation for members of the naval service who are chaplains. This should not be construed, however, as restricting or excluding solicitation for information which the individual is willing to have in his record concerning religious preference, particularly that required in emergency situations.

(5) Records used by the Department of the Navy in making determinations about an individual will be maintained with such accuracy, relevance, timeliness, and completeness as is reasonably necessary to ensure fairness to the individual in any determination concerning him.

(b) *Responsibilities.* (1) Each addressee is responsible for implementing and executing the purposes and requirements of 5 U.S.C. 552a within his organization, in accordance with the provisions of this subpart.

(2) The Chief of Naval Operations (Op-09B) is responsible for administering and supervising the execution of 5 U.S.C. 552a and this subpart within the Department of the Navy. Additionally, the Chief of Naval Operations (Op–09B1) is designated as the principal Privacy Act coordinator for the Department of the Navy.

(3) The Commandant of the Marine Corps is responsible for administering and supervising the execution of 5 U.S.C. 552a and this subpart within the Marine Corps.

(c) *Denial authority.* Only the following officials (and their respective deputies, principal assistants, or designees) are authorized to deny requests for notification, access, and amendment made under this subpart, when the records relate to matters within their respective areas of command, area coordination, technical, or administrative responsibility, as appropriate:

(1) In the Navy Department, the Civilian Executive Assistants, the Chief of Naval Operations, the Commandant of the Marine Corps, the Chief of Naval Material, the Chief of Naval Personnel, the Chief, Bureau of Medicine and Surgery, the heads of Department of the Navy Staff Offices, Boards, and Councils, the Auditor General of the Navy, the Naval Inspector General, and the Assistant Judge Advocate General (Civil Law).

(2) In the Shore Establishment, Commanders of Naval Systems Commands; the Commanders of the Naval Intelligence Command, Naval Security Group Command, and Naval Telecommunications Command; the Chiefs of Naval Education and Training, Naval Air Training, and Naval Technical Training; the President, Naval War College; the Superintendent, Naval Postgraduate School; the Superintendent, the U.S. Naval Academy; the Chief of Naval Reserve; the Oceanographer of the Navy; and Commandants of Naval Districts.

(3) In the Operating Forces, CIN CLANT, CINCPAC, Fleet Commanders in Chief, Force Commanders, Type Commanders, and the Commander, Military Sealift Command.

(4) Commanders of major Navy and Marine Corps activities designated by the Chief of Naval Operations or the Commandant of the Marine Corps.

(d) *Review authority.* (1) The Assistant Secretary of the Navy (Manpower and Reserve Affairs), as the Secretary's designee, shall act upon requests for administrative review of initial denials of requests for amendment of records of fitness reports and performance evaluations of military personnel.

(2) The Judge Advocate General, as the Secretary's designee, shall act upon requests for administrative review of initial denials of requests for notification, access, or amendment of records, other than as indicated in paragraph (d)(1) of this section and other than initial denials of requests for notification, access, or amendment of records from civilian Official Personnel Folders or records contained on any other Civil Service Commission forms.

(e) *Law enforcement activity requests for records from non-DOD agencies.* The authority to request records from a civil or criminal law enforcement agency outside of DOD, under subsection (b)(7) of 5 U.S.C. 552a, is delegated to the Commandant of the Marine Corps, the Director of Naval Intelligence, the Judge Advocate General, and the General Counsel. These officials may further delegate this authority to deputies, assistants, and other subordinates who exercise authority over an office or division.

§ 701.105 Definitions.

For the purposes of this subpart, the following meanings apply:

(a) *Individual.* A citizen of the United States, or an alien lawfully admitted for permanent residence; or an enlistee in the United States naval service, including a minor. Additionally, the legal guardian of an individual or a parent of a minor has the same rights as the individual, and may act on behalf of the individual concerned under this subpart. Members of the naval service, once properly accepted, are not minors for purposes of this subpart. The use of the term "individual" does not, however, vest rights in the representatives of decedents to act on behalf of the decedent under this subpart, nor does the term embrace individuals acting in an entrepreneurial capacity (e.g., sole proprietorships and partnerships).

(b) *Maintain.* When used in the context of records on individuals, includes collect, file or store, preserve, retrieve, update or change, use, or disseminate.

(c) *Record.* Any item, collection, or grouping of information about an individual that is maintained by or for the Department of the Navy or by any element of the Navy Department, operating forces, or shore establishment, including, but not limited to, his education, financial transactions, medical history, qualifications, service data, and criminal or emplovment history, and which contains his name, or the identifying number, symbol, or other identifying particular assigned to the individual, such as a finger or voice print or a photograph.

(d) *System of records.* A group of records under the control of the Department of the Navy or of any element of the Navy Department, operating forces, or shore establishment, from which information is retrieved by the name of the individual or by some identifying number, symbol, or other identifying particular assigned to the individual.

(e) *System manager.* That official who has overall responsibility for records within a particular system. System managers are indicated in the published record system notices. If more than one official is indicated as a system manager, initial contact should be established at the appropriate level (e.g., for local records, contact should be made at the local level).

(f) *Routine use.* When used with respect to the disclosure of a record, the use of a record in compliance with the section of the published record system notice specifying "routine uses," provided such use is compatible with the purpose for which the record was collected. Normally this term is used in connection with interagency transfers of records, rather than transfers within the Department of Defense and the Department of the Navy.

(g) *Disclosure.* The conveyance of any information from a record by any means of communication to any other person or entity.

§ 701.106 Notification, access, and amendment procedures.

(a) *General.* (1) *Summary of requirements.* (i) "Notification" procedures are provided under subsection (e)(4) of 5 U.S.C. 552a to enable an individual to ascertain from the appropriate system manager whether or not a particular system of records contains information pertaining to him. If the system does contain such a record, the individual may request "access" to the record, pursuant to subsection (d)(1) of 5 U.S.C. 552a, to ascertain the contents. "Amendment" procedures are provided under subsections (d) (2) and (3) of 5 U.S.C. 552a, to enable the individual to seek correction or deletion of information about himself in the record which he considers to be erroneous. If a request for "amendment" is denied after a final determination, the individual may file a "statement of dispute," to be noted in the pertinent records and to be shown in connection with disclosures of such records. Individuals have a statutory right to obtain administrative review of denials of requests for amendment, and, by this subpart, are accorded the right to obtain similar review of denials of requests for notification and access.

(ii) The provisions of this paragraph apply to requests by individuals, or their authorized representatives, for records pertaining to themselves that are contained in systems of records, even though the requests specify that they are made pursuant to the Freedom of Information Act or other authority. This subpart does not, however, require that an individual be given notification or access to a record that is not retrieved by name or other individual identifier. Requests for amendment of records—whether or not contained in a system of records—will normally be processed in accordance with this instruction, unless: (A) They are routine requests for administrative corrections not specifying that they are made under this subpart or 5 U.S.C. 552a, or (B) They are requests addressed to the Board for Correction of Naval Records, which is governed by other authority.

(2) *System "rules."* System managers are responsible for ensuring that, for each system of records maintained, a record system notice is published in the

FEDERAL REGISTER, stating the procedures by which an individual may be notified whether the system contains records pertaining to him. Additionally, system managers are responsible for establishing, and making available to individuals upon request, rules applicable to requests for access or amendment of records within each system. Such rules must conform to the requirements of this subpart and § 701.117. In addition, they should contain the following:

(i) A statement of custodial officials other than the system manager, if any, authorized to grant requests for notification or access;

(ii) The minimum formal requirements for requests, including applicable requirements for requests to be reduced to writing; and, in the case of a request to provide the requester's records directly to an authorized representative who is other than the parent of a minor, or other legal guardian—a recently signed authorization specifying the records to be released and the recipient of the records (notarized authorizations may be required if the sensitivity of the information in the records warrants);

(iii) The information which should be provided by the individual to assist in identifying relevant systems of records and the individual identifiers (e.g., full name, social security number, etc.) needed to locate records in the particular system; and

(iv) The requirements for verifying the requester's identity, to which the following policies apply:

(A) Prior to being given notification or access to personal information, an individual is generally required to provide reasonable verification of his identity. No verification of identity, however, shall be required of an individual seeking notification or access to records which are otherwise available to any member of the public under 32 CFR Part 701, subparts A–D.

(B) In the case of an individual who seeks notification, access, or amendment in person, verification of identity will normally be made from those documents that an individual is likely to have readily available, such as an employee or military identification card, driver's license, or medical card.

(C) When notification, access, or amendment is requested by mail, verification of identity may be obtained by requiring the individual to provide certain minimum identifying data, such as date of birth and some item of information in the record that only the concerned individual would likely know. If the sensitivity of the information in the record warrants, a signed and notarized statement of identity may be required.

(D) When a record has already been identified, an individual shall not be denied notification or access solely for refusing to disclose his social security number.

(3) *Responsibilities for action of initial requests.* (i) Subject to the provisions of this paragraph and the applicable system manager's rules, requests for notification and access may be granted by officials having custody of the records, even if they are not system managers or denial authorities. Requests for amendment may be granted by the cognizant system manager. Denials of initial requests for notification, access, or amendment of records under this instruction, however, may be made only by those officials designated as denial authorities under paragraph (c) of § 701.104.

(ii) Copies of investigatory records that are compiled by an investigative organization, but are in the temporary custody of another organization, which is holding the record for disciplinary, administrative, judicial, investigative, or other purposes, are the records of the originating investigative organization. Upon completion of the official action, the investigative reports are required to be destroyed or returned, in accordance with the instructions of the originating investigative agency. Individuals seeking notification or access, or making other requests under this instruction concerning such records, shall be directed to the originating investigative organization. For example, a request for notification or access to a Naval Investigative Service report in the temporary custody of another activity should be forwarded directly to the Director, Naval Investigative Service.

(4) *"Blanket" requests not honored.* Requests seeking notification and/or access concerning all systems of records within the Department of the Navy, or a component thereof, shall not be honored. Individuals making such requests shall be notified that:

(i) Requests for notification and/or access must be directed to the appropriate system manager for the particular record system, as indicated in the current FEDERAL REGISTER record system notice (a citation should be provided), and

(ii) Requests must either designate the particular system of records to be searched, or provide sufficient information for the system manager to ascertain the appropriate system. Individuals should also be provided with any other information needed for obtaining consideration of their requests.

(5) *Criteria for determinations.* (i) as further explained in § 701.111, portions of designated records systems (indicated in subpart G of this part) are exempt, in certain circumstances, from the requirement to provide notification, access, and/or amendment. Only denial authorities (and the designated review authority) may exercise an exemption and deny a request, and then only in cases where there is specifically determined to be a significant and legitimate governmental purpose served by denying the request. A request for notification may be denied only when an applicable exemption has been exercised by a deniel or review authority. A request for access may be denied by a denial or review authority, in whole or part, on the basis of the exercise of an applicable exemption or for the reasons set forth in § 701.106(a)(5)(ii) or (iii).

(ii) Where a record has been compiled in reasonable anticipation of a civil action or proceeding, a denial authority (or the designated review authority) may deny an individual's request for access to that record pursuant to subsection (d)(5) of 5 U.S.C. 552a, provided that there is specifically determined to be a significant and legitimate governmental purpose to be served by denying the request. Consultation with the Office of the Judge Advocate General, Office of General Counsel, or other originator, as appropriate, is required prior to granting or denying access to attorney-advice material. This includes, but is not limited to, legal opinions.

(iii) Where a denial authority, or the designated review authority, determines that the grant of access to the entire contents of a record to the requesting individual would result in a clearly unwarranted invasion of the personal privacy of another individual mentioned in the same record, and such other individual has not furnished his written consent for the record to be disclosed to the requester, the portion of the record that pertain solely to such other individual shall be deleted from a copy of the record. The requesting individual shall then be granted access to a copy of the remaining portions of the record.

(iv) As indicated in § 701.105(a), where a record pertains to an individual who is a minor, the minor's parent or legal guardian is normally entitled to obtain notification concerning, and access to, the minor's record, pursuant to the provisions of this paragraph. When, however, an applicable law or regulation prohibits notification to, or access by, a parent or legal guardian with respect to a particular record, or portions of a record, pertaining to a minor, the provisions of the governing law or regulation and § 701.107, shall govern disclosures of the existence or contents of such records to the minor's parent or legal guardian. (Members of the naval service, once properly accepted, are not minors for the purposes of this subpart.)

(v) Subject to the provisions of this paragraph, a medical record shall be made available to the individual to whom it pertains unless, in the judgment of a physician, access to such record could have an adverse effect upon the individual's physical or mental health. When it has been determined that granting access to medical information could have an adverse effect upon the individual to whom it pertains, the individual may be asked to name a physician to whom the information shall then be transmitted. This shall not be deemed a denial of a request for access.

(vi) Criteria for determinations on requests for amendment of records are set forth in § 701.106(d)(1).

(6) *Time requirements for making acknowledgements and determinations.* (i) A request for notification, access, or amendment of a record shall be acknowledged in writing within 10 working days (Saturdays, Sundays, and legal holidays excluded) of receipt by the proper of-

fice. The acknowledgement shall clearly identify the request and advise the individual when he may expect to be advised of action taken on the request. No separate acknowledgement of receipt is necessary if a request for notification or access can be acted upon, and the individual advised of such action, within the 10-working-day period. If a request for amendment is presented in person, written acknowledgement may be provided at the time the request is presented.

(ii) Determinations and required action on initial requests for notification, access, or amendment of records shall be completed, if reasonably possible, within 30 working days of receipt by the cognizant office.

(b) *Notification procedures.* (1) *Action upon receipt of request.* Subject to the provisions of this paragraph, upon receipt of an individual's initial request for notification, the system manager or the other appropriate custodial official shall acknowledge the request as required by § 701.106(a)(6)(i) and take one of the following actions:

(i) If consideration cannot be given to the request, because—

(A) The individual's identity is not satisfactorily verified;

(B) The record system is not adequately identified, or the individual has not furnished the information needed to locate a record within the system; or

(C) The request is erroneously addressed to an official having no responsibility for the record or system of records in question—

inform the individual of the correct means, or additional information needed, for obtaining consideration of his request for notification;

(ii) Notify the individual, in writing, whether the system of records contains a record pertaining to him (a notification that a system of records contains no records pertaining to the individual shall not be deemed a denial of a request for notification or access);

(iii) If it is determined that notification should be denied under an available exemption and the official is not a denial authority, forward the request to the cognizant denial authority, with a copy of the requested record, and comments and recommendations concerning disposition; or

(iv) If the official is a denial authority, take the appropriate action prescribed in § 701.106(b)(2).

(2) *Action by denial authority.* (i) If the denial authority determines that no exemption is available or that an available exemption should not be exercised, he shall provide the requested notification, or direct the system manager or appropriate custodial authority to do so.

(ii) If the denial authority determines that an exemption is applicable and that denial of the notification would serve a significant and legitimate governmental purpose (e.g., avoid interfering with an on-going law enforcement investigation), he shall promptly send the requesting individual an original and one copy of a letter stating that no records from the system of records specified in the request are available to the individual under the Privacy Act. The letter shall also inform the individual that he may request further administrative review of the matter within 120 days, by letter to the:

Judge Advocate General (Code 14L), Department of the Navy, Washington, DC 20370.

The individual shall be further informed that a letter requesting such review should contain the enclosed copy and a statement of the individual's reasons for requesting the review.

(iii) A copy of the letter denying notification shall be forwarded directly to the Chief of Naval Operations (Op-09B1) or the Commandant of the Marine Corps (Code M), as appropriate. These officials shall maintain copies of all denial letters in a form suitable for rapid retrieval, periodic statistical compilation, and management evaluation.

(3) *Action by reviewing authority.* Upon receipt of a request for review of a determination denying an individual's initial request for notification, the Judge Advocate General shall obtain a copy of the case file from the denial authority, review the matter, and make a final administrative determination. He is designated to perform such acts as may be required by or on behalf of the Secretary of the Navy to accomplish a thorough review and to effectuate the determination. Within 30 working days of receipt of the request for review, whenever practicable, the Judge Advocate General shall inform the requesting individual, in writing, of the final determination and the action thereon. If the final determination is to grant notification, the Judge Advocate General may either provide the notification or direct the system manager to do so. If the final determination is to deny notification, the individual shall be informed that it has been determined upon review that there are no records in the specified system of records that are available to him under the Privacy Act.

(c) *Access procedures.* (1) *Fees.* When a copy of a record is furnished to an individual in response to a request for access, he will normally be charged duplication fees determined in accordance with § 701.40, unless such fees are waived. If the individual requests that his record be made available for review in person and copying is the only means by which the record can be shown to him (e.g., when a copy must be made in order to delete information pertaining to another individual in the record), a duplication fee shall not be charged. Search fees are not assessable under the Privacy Act. Civil Service Commission Regulation 297.115 will be used to determine the fees to be charged for copying records from CSC Government-wide systems of records.

(2) *Action upon receipt of request.* Subject to the provisions of this paragraph, upon receipt of an individual's initial request for access, the system manager or other appropriate custodial official shall acknowledge the request as required by § 701.106(a)(6)(i), and take one of the following actions:

(i) If consideration cannot be given to the request because—

(A) The individual's identity is not satisfactorily verified;

(B) The record system is not adequately identified or the individual has not furnished the information needed to locate a record within a system; or

(C) The request is erroneously addressed to an official not having responsibility for granting access to the record or system of records in question—

inform the individual of the correct means, or additional information needed, for obtaining consideration of his request for access;

(ii) If it is determined that the individual should be granted access to the entire record requested, the official shall inform the individual, in writing, that access is granted, and shall either:

(A) Inform the individual that he may review the record at a specified place and at specified times, that he may be accompanied by a person of his own choosing to review the record (in which event he may be asked to furnish written authorization for the record to be discussed in the accompanying person's presence), and that he may further obtain a copy of the record upon agreement to pay a duplication fee; or

(B) Furnish a copy of the record, if the individual requested that a copy to be sent and agreed in advance to pay duplication fees determined in accordance with § 701.40, unless such fees are waived.

(iii) If it is necessary to deny the individual access to all or part of the requested record, and—

(A) The official is not a denial authority—forward the request to the cognizant denial authority, with a copy of the requested record, and comments and recommendations concerning disposition; or

(B) The official is a denial authority—take the action prescribed in 701.106(c)(3)(i) or (ii) as appropriate.

(3) *Action by denial authority.* (i) If the denial authority determines that access should be granted to the entire record, he shall promptly make it available to the requesting individual in the manner prescribed in § 701.106(c)(2)(i), or direct the system manager to do so.

(ii) If the denial authority determines that access to the entire record should be denied under the criteria specified in paragraph (a)(5)(i), (ii), or (iii) of this section, he shall promptly send the requesting individual an original and one copy of a letter informing the individual of the denial of access and the reasons therefor, including citation of any applicable exemptions and a brief discussion of the significant and legitimate governmental purpose(s) served by the denial of access. The denial letter shall also inform the individual that he may request further administrative review of the matter within 120 days, by letter:

(A) If the record is from a civilian Official Personnel Folder or is contained on any other Civil Service Commission form, to—

Director, Bureau of Manpower Information Systems, U.S. Civil Service Commission, 1900 E Street NW., Washington, DC 20415; or

(B) If for any other record, to—

Judge Advocate General (Code 14L), Department of the Navy, Washington, DC 20370.

The individual shall be further informed that a letter requesting such review should contain the enclosed copy of the denial letter and a statement of the individual's reasons for seeking review of the initial determination.

(iii) A copy of the denial letter shall be forwarded directly to the Chief of Naval Operations (Op–09B1) or the Commandant of the Marine Corps, (Code M) as provided in paragraph (b)(2)(iii) of this section.

(iv) If the denial authority determines that access to portions of the record should be denied under the criteria specified in paragraph (a)(5)(i), (ii), or (iii) of this section, he shall promptly make an expurgated copy of the record available to the requesting individual and issue a denial letter, in the manner and form provided in the preceding paragraph, as to the portions of the record that are required to be deleted.

(4) *Action by reviewing authority.* Upon receipt of a request for review of a determination denying an individual's initial request for access, the Judge Advocate General shall obtain a copy of the case file from the denial authority, review the matter, and make a final administrative determination. He is designated to perform such acts as may be required by or on behalf of the Secretary of the Navy to accomplish a thorough review and to effectuate the determination.

(i) Within 30 days of receipt of the request for review, if practicable, the Judge Advocate General shall inform the requesting individual, in writing, of the final determination and the action thereon.

(ii) If such determination has the effect of granting a request for access, in whole or in part, the Judge Advocate General may either provide access in accordance with paragraph (c)(2)(ii)(A) or (B) of this section, or direct the system manager to do so.

(iii) If the final determination has the effect of denying a request for access, in whole or part, the individual shall be informed of the reason(s) and statutory basis for the denial—including regulatory citations for any exemption exercised and an explanation of the significant and legitimate governmental purpose served by exercising the exemption—and of his rights to seek judicial review.

(iv) If the determination is based, in whole or part, on a security classification, the individual shall be apprised of the matters set forth in § 701.9(d)(4)(ii) of this Subpart relating to declassification review and appeal.

(d) *Amendment procedures.* (1) *Criteria for determinations on requests for amendment.* (i) As further explained in § 701.111 of this Subpart, many of the systems of records listed in subpart G are exempt, in part, from amendment requirements. Such exemptions, where applicable, may be exercised only by denial authorities (and by the designated review authorities upon requests for review of initial denials), and then only in cases where there is specifically determined to be a significant and legitimate governmental purpose to be served by exercising the exemption.

(ii) If an available exemption is not exercised an individual's request for amendment of a record pertaining to himself shall be granted if it is determined, on the basis of the information presented by the requester and all other reasonably available related records, that the requested amendment is warranted in order to make the record sufficiently accurate, relevant, timely, and complete as to ensure fairness in any determination which may be made about the individual on the basis of the record. If the requested amendment would involve the deletion of particular information from the record, the information shall be deleted unless it is determined that—in addition to being accurate, relevant to the individual, timely, and complete—the information is relevant and necessary to accomplish a purpose or function required to be performed by the Department of the Navy pursuant to a statute or Executive order.

(iii) The foregoing is not intended to permit the alteration of evidence presented in the course of judicial or quasi-judicial proceedings. Any changes in such records should be made only through the procedures established for changing such records. These provisions are also not designed to permit collateral attack upon that which has already been the subject of a judicial or quasi-judicial action. For example, an individual would not be permitted to challenge a court-martial conviction under this subpart, but the individual would be able to challenge the accuracy with which a conviction has been recorded in a record.

(iv) As indicated in paragraph (a)(1) of this section, the procedures in this paragraph are generally applicable to requests for amendment of records, irrespective of whether a particular record is contained in a system of records, provided that it can be identified and located.

(2) *Action upon receipt of request.* Subject to the provisions of this paragraph, upon receipt of an individual's initial request for amendment of a record, the system manager (or official occupying a comparable position with respect to a record not contained in a system of records) shall acknowledge the request in the manner prescribed by paragraph (a)(6)(i) of this section and, within 30 days, if reasonably possible, take one of the following actions:

(i) If consideration cannot be given to the request because—

(A) The individual's identity is not satisfactorily verified;

(B) The individual has not furnished the information needed to locate the record;

(C) The individual has not provided adequate information as to how or why the record should be amended; or

(D) The request is erroneously addressed to an official having no responsibility for the record or system of records in question—

inform the individual of the correct means, or additional information needed, for obtaining consideration of his request for amendment (a request may not be rejected, nor may the individual be required to resubmit his request, however, unless this is essential for processing the request);

(ii) If the system manager determines that the individual's request to amend a record is warranted under the criteria in paragraph (d)(1) of this section, he shall promptly amend the record and advise the individual, in writing, of that action and its effect. The system manager also should attempt to identify other records affected by the requested amendment and should make other necessary amendments, accordingly. Amendments to records should be made in accordance with existing directives and established procedures for changing records, if applicable and consistent with this subpart. The system manager shall advise previous recipients of the record for whom a disclosure accounting has been made that the record has been amended, and of the substance of the correction;

(iii) If the system manager is a denial authority, and denial of the request for amendment, in whole or part, is warranted, take the appropriate action prescribed in paragraph (d)(3)(ii) or (iii) of this section; or

(iv) If the system manager is not a denial authority, but denial of the request for amendment, in whole or part, appears to be warranted, forward the request to the cognizant denial authority with a copy of the disputed record, and comments and recommendations concerning disposition.

(3) *Action by denial authority.* (i) If the denial authority determines that amendment of the record is warranted under the criteria in paragraph (d)(1) of this section, he shall direct the system manager to take the action prescribed in paragraph (d)(2)(ii) of this section.

(ii) If the denial authority determines that amendment of the record is not warranted under the criteria in paragraph (d)(1) of this section, he shall promptly send the requesting individual an original and one copy of a letter informing him of the denial of the request and the reason(s) for the denial, including a citation of any exemption exercised and a brief discussion of the significant and legitimate governmental purpose(s) served by exercising the exemption. The denial letter shall inform the individual that he may request further administrative review of the matter, as follows:

(A) If the record is a fitness report or performance evaluation (including proficiency and conduct marks) from a military personnel file—by letter, within 120 days, to:

Assistant Secretary of the Navy (Manpower and Reserve Affairs), Department of the Navy, Washington, DC 20350; or

(B) If the record is from a civilian Official Personnel Folder or is contained in any other Civil Service Commission form—by letter, within 30 days, to:

Director, Bureau of Manpower Information Systems U.S. Civil Service Commission, 1900 E Street, NW., Washington, DC 20415; or

(C) For any other record—by letter, within 120 days, to:

Judge Advocate General (Code 14L), Department of the Navy, Washington, DC 20370.

The individual shall be further informed that a letter requesting such review should contain the enclosed copy of the denial letter and a statement of the reasons for seeking review of the initial determination denying the request for amendment. A copy of the denial letter shall be forwarded to the Chief of Naval Operations or Commandant of the Marine Corps, as provided in paragraph (b)(2)(iii) of this section.

(iii) If the denial authority determines that a request for amendment of a record should be granted in part and denied in part, he shall take the action prescribed in paragraph (d)(3)(ii) of this section with respect to the portion of the request which is granted, and the action prescribed in paragraph (d)(3)(ii) of this section with respect to the portion of the request which is denied.

(4) *Action by reviewing authority.* Upon receipt of a request for review of a determination denying an individual's initial request for amendment of a record, the Assistant Secretary of the Navy (Manpower and Reserve Affairs) or the Judge Advocate General, as appropriate, shall obtain a copy of the case file from the denial authority, review the matter, and make a final administrative determination, either granting or denying amendment, in whole or in part. Those officials are designated to perform such acts as may be required by or on behalf of the Secretary of the Navy to accomplish a thorough review and effectuate the determination.

(i) Within 30 working days of receipt of the request for review, the designated reviewing official shall inform the requesting individual, in writing, of the final determination and the action thereon, except that the Assistant Secretary of Navy (Manpower and Reserve Affairs) may authorize an extension of the time limit where warranted because a fair and equitable review cannot be completed within the prescribed time, or for other good cause. If an extension is granted, the requesting individual shall be informed, in writing, of the reason for the delay, and the approximate date on which the review will be completed and the final determination made.

(ii) If, upon completion of review, the reviewing official determines that denial of the request for amendment is warranted under the criteria in paragraph (d)(1) of this section, the individual shall be informed, in writing:

(A) Of the final denial of the request for amendment of the record, and the reason(s) therefor;

(B) Of the right to file with the appropriate system manager a concise statement of the individual's reason(s) for disagreeing with the decision of the agency, and that such statement of dispute must be received by the system manager within 120 days following the date of the reviewing authority's final determination;

(C) Of other procedures for filing such statement of dispute, and that a properly filed statement of dispute will be made available to anyone to whom the record is subsequently disclosed, together with, if deemed appropriate, a brief statement summarizing the reason(s) why the Department of the Navy refused the request to amend the record;

(D) That prior recipients of the disputed record will be provided a copy of the statement of dispute, to the extent that the prior recipients can be ascertained from disclosure accountings which have been maintained; and

(E) Of his right to seek judicial review of the reviewing authority's refusal to amend a record.

(iii) If the reviewing official determines upon review that the request for amendment of the record should be granted, he shall inform the requesting individual of the determination, in writing, and he shall direct the system manager to amend the record accordingly, and to inform previous recipients of the record for whom disclosure accountings have been made that the record has been amended and the substance of the correction.

(iv) *Statements of dispute.* When an individual properly files a statement of dispute under the provisions of paragraph (d)(4)(ii) and (iii) of this section, the system manager shall clearly annotate the record so that the dispute is apparent to anyone who may subsequently access, use, or disclose it. The notation itself should be integral to the record. For automated systems of records, the notation may consist of a special indicator on the entire record or on the specific part of the record in dispute. The system manager shall advise previous recipients of the record for whom accounting disclosure has been made that the record has been disputed, if the statement of dispute is germane to the information disclosed, and shall provide a copy of the individual's statement.

(A) The individual's statement of dispute need not be filed as an integral part of the record to which it pertains. It shall, however, be maintained in such a manner as to permit ready retrieval whenever the disputed portion of the record is to be disclosed. When information which is the subject of a statement of dispute is subsequently disclosed, the system manager shall note that the information is disputed, and provide a copy of the individual's statement of dispute.

(B) The system manager may include a brief summary of the reasons for not making an amendment when disclosing disputed information. Summaries normally will be limited to the reasons stated to the individual. Although these summaries may be treated as a part of the individual's record, they will not be subject to the amendment procedures of this paragraph.

§ 701.107 Disclosure to others and disclosure accounting.

(a) *Summary of requirements.* Subsection (b) of 5 U.S.C. 552a prohibits an agency from disclosing any record contained in a system of records to any person or agency, except pursuant to the written request or consent of the individual to whom the record pertains, unless the disclosure is authorized under one or more of the 11 exceptions noted in paragraph (b) of this section. Subsection (i)(1) of 5 U.S.C. 552a prescribes criminal penalties for personnel who knowingly and willfully make unauthorized disclosures of information about individuals from an agency's records. Subsection (c) of 5 U.S.C. 552a requires accurate accountings to be kept, as prescribed in paragraph (c) of this section in connection with most disclosures of a record pertaining to an individual (including disclosures made pursuant to the individual's request or consent). This is to permit the individual to determine what agencies or persons have been provided information from the record, enable the agency to advise prior recipients of the record of any subsequent amendments or statements of dispute concerning the record, and provide an audit trail for review for the agency's compliance with 5 U.S.C. 552a.

(b) *Conditions of disclosure.* No record contained in a system of records shall be disclosed, except pursuant to a written request by, or with the prior written consent of, the individual to whom the record pertains, unless disclosure of the record falls within one of the exceptions specified below. Disclosure to third parties on the basis of the written consent or request of the individual is permitted, but not required, by this subpart.

(1) *Intra-agency.* Disclosure may be made to personnel of the Department of the Navy or other component of DoD (including private contractor personnel who are engaged to perform services needed in connection with the operation of a system of records for a DoD component), who have a need for the record in the performance of their duties, provided this use is compatible with the purpose for which the record is maintained. This provision is based on the "need to know" concept.

(i) This may include, for example, disclosure to personnel managers, review boards, discipline officers, court-martial personnel, medical officers, investigating officers, and representatives of the Judge Advocate General, Auditor General, Naval Inspector General, or the Naval Investigative Service, who require the information in order to discharge their official duties. Examples of person-

nel outside the Navy who may be included are: personnel of the Joint Chiefs of Staff, Armed Forces Entrance and Examining Stations, Defense Investigative Service, or the other military departments, who require the information in order to discharge an official duty.

(ii) It may also include a transfer of records between naval components and non-DOD agencies in connection with the Personnel Exchange Program (PEP) and interagency support agreements. Disclosure accountings are not required for intra-agency disclosure and disclosures made in connection with interagency support agreements or the PEP. Although some disclosures authorized by this paragraph might also meet the criteria for disclosure under other exceptions specified in the following paragraphs, they should be treated under paragraph (d)(1) of this section for disclosure accounting purposes.

(2) *Freedom of Information Act.* Disclosure may be made of those records, or information obtained from the records, required to be released under the provisions of the Freedom of Information Act and 32 CFR Part 701, subparts A–D. That act has the general effect of requiring the release of any record which does not fall within one of the nine exemptions specified in § 701.5(b)(4)(ii), including an exemption for records which, if disclosed, would result in a clearly unwarranted invasion of the personal privacy of an individual. Examples of information pertaining to military personnel which is normally released are: name, rank or rate, date of rank, amounts of pay and allowances included in gross compensation, duty status, present and past duty stations, duty station address, finalized future duty station, office phone number, source of commission, military and civilian educational level, and promotion sequence number. Similar examples pertaining to civilian employees are: name, grade, duty station, date of employment, title or position, gross salary, office phone number, and office address. The information specified in the above examples may be provided without requiring a written request. For guidelines concerning disclosure of other items of information pertaining to individuals, see 32 CFR Part 701, subpart B. Disclosure accountings are not required for disclosures made under the Freedom of Information Act.

(3) *Routine use.* Disclosure may be made for a "routine use" (as defined in § 701.105(f)) that is compatible with the purpose for which the record is collected and listed as a routine use in the applicable record system notice published in the FEDERAL REGISTER in accordance with § 701.108 of this subpart. The routine uses listed in the applicable record system notice, rather than those listed in the applicable Privacy Act statement, are controlling, although the lists should be similar. Disclosure accountings are required for disclosures made pursuant to a routine use.

(4) *Bureau of the Census.* Disclosure may be made to the Bureau of the Census for purposes of planning or carrying out a census or survey or related activity authorized by law. Disclosure accountings are required for disclosures made to the Bureau of the Census.

(5) *Statistical research or reporting.* Disclosure may be made to a recipient who has provided adequate written assurance that the record will be used solely as a statstical research or reporting record, provided the record is transferred in a form that is not individually identifiable (i.e., the identity of the individual cannot be deduced by tabulation or other methodology). The written request must state the purpose of the request, and will be made a part of the activity's accounting for the disclosure. Accountings are not required when activities publish gross statistics concerning a population in a system of records (e.g., statistics on employee turnover rates, military reenlistment rates, and sick leave usage rates).

(6) *National Archives.* Disclosure may be made to the National Archives when the record has sufficient historical or other value to warrant continued preservation by the U.S. Government, or for evaluation by the Administrator of General Services or his designee to determine whether the record has such value. Records transferred to a federal records center for storage or safekeeping do not fall under this provision. Such transfers are not considered disclosures under this act, since the records remain under the control of the transferring element. Accounting is not required for transfers of records to federal records centers. Disclosure accountings are required for disclosures made to the National Archives.

(7) *Civil or criminal law enforcement activity.* Disclosure may be made to another agency or instrumentality of any governmental jurisdiction within or under the control of the United States, for a civil or criminal law enforcement activity, if the activity is authorized by law, and if the head of the agency or instrumentality has made a written request to the activity which maintains the record, specifying the particular record desired and the law enforcement purpose for which the record is sought. The head of the agency or instrumentality may have delegated authority to request records to other officials. Requests by these designated officials shall be honored if they provide satisfactory evidence of their authorization to request records. Blanket requests for all records pertaining to an individual shall not be honored. A record may also be disclosed to a law enforcement activity, provided that such disclosure has been established as a "routine use" in the published record system notice. Disclosure to foreign law enforcement agencies is not covered under the provisions of this paragraph. Such disclosures may be made only pursuant to an established "routine use" published in the record system notice or pursuant to other governing authority. Disclosure accountings are required for disclosures to civil or criminal law enforcement agencies.

(8) *Emergency conditions.* Disclosure may be made under emergency conditions involving compelling circumstances affecting the health and safety of a person, provided that notification of the disclosure is transmitted to the last known address of the individual to whom the record pertains. For example, an activity may disclose records when the time required to obtain the consent of the individual to whom the record pertains might result in a delay which could impair the health or safety of a person. The individual about whom the records are disclosed need not necessarily be the individual whose health or safety is in peril (e.g., release of dental charts on several individuals in order to identify a person injured in an accident). In instances where information under alleged emergency conditions is requested by telephone, an attempt will be made to verify the inquirer's and medical facility's identities and the caller's telephone number. The requested information, if then considered appropriate and of an emergency nature, may be provided by return call. Disclosure accountings are required for disclosures made under emergency conditions.

(9) *Congress and Members of Congress.* Disclosure may be made to either House of Congress, or, to the extent of matters within its jurisdiction, to any committee or subcommittee thereof, or to any joint committee of Congress or subcommittee thereof. Disclosure may not be made, however, to a Member of Congress requesting in his individual capacity or on behalf of a constituent, except in accordance with the following rules:

(i) Upon receipt of an oral or written request from a Member of Congress or his staff, inquiry should be made as to the identity of the originator of the request. If the request was prompted by a request for assistance by the individual to whom the record pertains, the requested information may be disclosed to the requesting Congressional office.

(ii) If the request was originated by a person other than the individual to whom the record pertains, the Congressional office must be informed that the requested information cannot be disclosed without the written consent of the individual to whom the record pertains. If the Congressional office subsequently states that it has received a request for assistance from the individual or has obtained the individual's written consent for disclosure to that office, the requested information may be disclosed.

(iii) If the Congressional office requests the Department of the Navy to obtain the consent of the individual to whom the record pertains, that office should be informed that it is the policy of the Department not to interfere in the relationship of a Member of Congress and his constituent, and that the Department therefore does not contact an individual who is the subject of a congressional inquiry.

(iv) If the Congressional office insists, an attempt should be made to secure the written consent of the individual to whom the record pertains. If neither the congressional office nor the Department of the Navy obtains the individual's written consent, only information required to be released under the Freedom of Information Act and 32 CFR Part 701, Subparts A–D should be disclosed. (See paragraph (b)(2) of this section).

Disclosure accountings are required for disclosures made to Congress or Members of Congress, except nonconsensual disclosures pursuant to the Freedom of Information Act provided for in paragraph (b)(9)(iv) of this section.

(10) *Comptroller General.* Disclosure may be made to the Comptroller General of the United States, or to any of his authorized representatives, in the course of the performance of the duties of the General Accounting Office. See § 701.103 (a)(3), above, and SECNAVINST 5741.-2E. Disclosure accountings are required for disclosures to the Comptroller General or General Accounting Office.

(11) *Court of competent jurisdiction.* Disclosure may be made in response to an order from a court of competent jurisdiction, subject to the following provisions:

(i) When a record is disclosed under compulsory legal process, and the issuance of that order is made public by the court which issued it, activities shall make reasonable efforts to notify the individual to whom the record pertains of the disclosure and the nature of the information provided. This requirement may be satisfied by notifying the individual by mail at the last known address contained in the activity records. Disclosure accountings are required for disclosures made pursuant to court orders.

(ii) Upon being served with an order which is not a matter of public record, an activity shall seek to be adivsed as to when it will become public. An accounting for the disclosure shall be made at the time the activity complies with the order, but neither the identity of the party to whom the disclosure was made nor the purpose of the disclosure shall be made available to the concerned individual unless the court order has become a matter of public record.

(c) *Disclosure accountings*—(1) *Responsibilities.* With respect to a disclosure of a record which it maintains in a system of records, each activity is responsible for keeping an accurate accounting of the date, nature, and purpose of the disclosure, and the name and address of the person or agency to whom the disclosure is made. When disclosure is made by an activity other than the activity that is responsible for maintaining the record, the activity making the disclosure is responsible for giving written notification of the above information to the activity responsible for maintaining the record, to enable the latter activity to keep the required disclosure accounting.

(2) *Disclosures for which accountings are required.* A disclosure accounting is required for all disclosures of records maintained in a system of records, except: intra-agency disclosures pursuant to paragraph 701.107(b)(1) of this section; Freedom of Information Act disclosures pursuant to paragraphs (b)(2) or (9)(iv) of this section; or, if they involve gross statistics covering a population of a system of records, and identification of individuals is not possible, disclosures for statistical research or reporting purposes pursuant to paragraph (b)(5) of this section. A disclosure accounting is required for a disclosure made to another person or agency pursuant to the request or consent of the individual to whom the record pertains. (There is no requirement for keeping an accounting for disclosures of disclosure accountings.)

(3) *Accounting method.* Since the characteristics of various records maintained within the Department of the Navy vary widely, no uniform method for keeping disclosure accountings is prescribed. For most paper records, it may be suitable to maintain the accountings on a record-by-record basis, physically affixed to the records. The primary criteria are that the selected method be one which will:

(i) Enable an individual to ascertain what persons or agencies have received disclosures pertaining to him;

(ii) Provide a basis for informing recipients of subsequent amendments or statements of dispute concerning the record; and

(iii) Provide a means to prove, if necessary, that the activity has complied with the requirements of 5 U.S.C. 552a and this subpart.

(4) *Retention of accounting record.* A disclosure accounting, if one is required, shall be maintained for the life of the record to which the disclosure pertains, or for at least five years after the date of the disclosure for which the accounting is made, whichever is longer.

(5) *Accounting to the individual.* Unless an applicable exemption has been exercised, system managers or other appropriate custodial officials shall provide all information in the disclosure accounting to an individual requesting such information concerning his records, except entries pertaining to disclosures made pursuant to paragraph (b)(1)(ii) of this section, and disclosures made at the written request of the head of another agency or government instrumentality for law enforcement purposes under paragraph (b)(7) of this section. Activities should maintain the accounting of the latter two types of disclosures in such a manner that the notations are readily segregable, to preclude improper release to the individual. The process of making the accounting available may also require transformation of the data in order to make it comprehensible to the individual. Requests for disclosure accountings otherwise available to the individual may not be denied unless a denial authority (or the designated review authority) has exercised an applicable exemption and denied the request, and then only when it has been determined that denial of the request would serve a significant and legitimate Government purpose (e.g., avoid interfering with an ongoing law enforcement investigation). System managers, denial authorities, and the designated review authority shall follow appropriate procedures prescribed in § 701.106(b), to exercise an exemption, to deny a request for an accounting of disclosures, and to review such denials.

(d) *Accuracy requirements.* Prior to disclosing any record about an individual to any person other than an agency, and other than pursuant to 5 U.S.C. 552a and 32 CFR Part 701, subparts A–D, reasonable efforts are required to ensure that such records are accurate, complete, timely, and relevant for Department of the Navy purposes. It may be appropriate to advise the recipient that the information was accurate as of a specific date, or otherwise give guidance concerning its quality.

(e) *Mailing lists.* No activity nor any member or employee of the Department of the Navy shall sell or rent individuals' names and addresses unless such action is specifically authorized by law. This provision should not be construed to require the withholding of names and addresses otherwise permitted to be made public.

§ 701.109 Collection of personal information from individual.

(a) *Collection directly from individuals.* Personal information shall be collected, to the greatest extent practicable, directly from the individual when the information may adversely affect an individual's rights, benefits, and privileges under Federal programs. The collection of information from third parties shall be minimized. Exceptions to this policy may be made when warranted. The following are examples, not necessarily exhaustive, of situations which may warrant exceptions:

(1) There is need to ensure the accuracy of information supplied by an individual by verifying it through a third party, e.g., verifying information for a security clearance;

(2) The nature of the information is such that it can be obtained only from a third party, such as supervisor's assessment of an employee's performance in a previous job or assignment; or

(3) Obtaining the information from the individual would present exceptional practical difficulties or would result in unreasonable cost.

(b) *Informing individuals from whom personal information is requested.* (1) Individuals who are asked to supply personal information about themselves for a system of records must be advised of:

(i) The authority (statute or Executive order) which authorizes the solicitation;

(ii) All major purposes for which the Department of Defense uses the information (e.g., pay entitlement, retirement eligibility, or security clearance);

(iii) A brief summary of those routine uses to be made of the information as published in the FEDERAL REGISTER, and distributed by SECNAV notice; and

(iv) Whether disclosure is mandatory or voluntary, and the possible consequences for failing to respond.

(2) This statement, which is referred to as a "Privacy Act statement," must be given regardless of the medium used in requesting the information, e.g., a blank sheet, preprinted form with a control number, format, questionnaire, survey sheet, or interview. It may be provided on the form used to collect the information, or on a separate form or sheet, a copy of which may be retained by the individual.

(3) When the privacy statement is to be attached or provided with the form, the statement will be assigned the same identifying number as the form used in collecting the information, and the suffix, "Privacy Act Statement." For example, a DD Form 398 would be identified as "DD Form 398—Privacy Act Statement." For unnumbered formats, such as questionnaires and survey report forms, the Privacy Act statement will bear the report control symbol, if one applies, or the OMB number, i.e., "OMB Approval No. 21—R0268, Privacy Act Statement." The statement will be positioned in such a manner that individuals from whom the information about themselves is being collected will be informed about the act before they begin to furnish any of the information requested.

(4) For the purpose of determining whether a Privacy Act statement is required, "personal information" should be considered to be information about an individual that is intimate or private to the individual, as distinguished from information related solely to the individual's official functions. It ordinarily includes, for example, information pertaining to an individual's financial, family, social, and recreational affairs; his medical, educational (other than military training), employment, or criminal history; or information that identifies, describes, or affords a basis for inferring personal characteristics, such as finger or voice prints or photographs. It ordinarily does not include such information as the time, place, and manner of, or reasons or authority for, an individual's execution or omission of acts directly related to the duties of his Federal employment or military assignment.

(5) The head of the proponent activity (i.e., the initiating or sponsoring activity) is responsible for determining whether a Privacy Act statement is required, and for ensuring that it is prepared and available as an attachment or as a part of the form, etc.

(c) *Requesting an individual's social security number (SSN).* Department of the Navy activities may not deny an individual any right, benefit, or privilege provided by law because the individual refuses to disclose his SSN, unless such disclosure is required by Federal statute or, in the case of systems of records in existence and operating before January 1, 1975, where such disclosure was required under statute or regulation adopted prior to January 1, 1975 to verify the identity of an individual. E.O. No. 9397 authorizes DoD components to use the SSN as a system of numerical identification of individuals.

(d) *Informing an individual when requesting his SSN.* (1) When an individual is requested to disclose his social security number, he must be informed:

(i) Whether such disclosure is mandatory or voluntary;

(ii) By what statutory or other authority the number is solicited; and

(iii) What uses will be made of it.

(2) An activity may request an individual's SSN even though it is not required by Federal statute, or is not for a system of records in existence and operating prior to January 1, 1975. However, the separate Privacy Act statement for the SSN, alone, or a merged Privacy Act statement, covering both the SSN and other items of personal information, must make clear that disclosure of the number is voluntary. If the individual refuses to disclose his SSN, the activity must be prepared to identify the individual by alternate means.

(3) Once a military member or civilian employee of the Department of the Navy has disclosed his SSN for purposes of establishing personnel, financial, or medical records upon entry into naval service or employment, the SSN becomes his service or employment identification number. It is not required that such an individual be informed of the items under paragraph (d)(1) of this section when he is subsequently requested to provide or verify this identification number in connection with those records.

§ 701.110 Safeguarding personal information.

(a) *Legislative requirement.* The Privacy Act requires establishment of appropriate administrative, technical, and physical safeguards to ensure the security and confidentiality of records, and to protect against any anticipated threats or hazards to their security or integrity which could result in substantial harm, embarrassment, inconvenience, or unfairness to any individual on whom information is required.

(b) *Responsibility.* At each location, and for each system of records, an official shall be designated as having responsibility for safeguarding the information therein. Specific safeguards for individual systems must be tailored to the existing circumstances, with consideration given to sensitivity of the data, need for continuity of operations, need for accuracy and reliability in operations, general security of the area, cost of safeguards, etc.

(c) *Minimum safeguards.* Ordinarily, personal information should be afforded at least the protection required for information designated as "For Official Use Only". (See SECNAVINST 5570.2B.) For privacy, the guideline is to provide reasonable safeguards to prevent inadvertent or unauthorized disclosures of record content, including during processing, storage, transmission, and disposal.

(d) *Automatic data processing.* The Director, Department of the Navy Automatic Data Processing Management is responsible for determining and formulating policies and procedures, as necessary, to ensure that ADP systems containing personal information contain adequate safeguards to protect personal privacy, and are in accordance with SECNAV INST 5230.4 and OPNAVINST 5510.1E.

(e) *Disposal.* Reasonable care must be taken to ensure that personal information is not subject to unauthorized disclosure during records disposal. If contractors are hired to haul trash containing personal information, contract provisions as specified in § 701.112 should be incorporated in the contract. If paper trash containing personal information is sold for recycling, legal assistance should be obtained to insert in the sale contract clauses that will make the buyer a Government contractor subject to the provisions of 5 U.S.C. 552a.

§ 701.111 Exemptions.

(a) *Summary.* Subsections (j) and (k) of 5 U.S.C. 552a authorize the Secretary of the Navy to adopt rules designating eligible systems of records as exempt from certain requirements of 5 U.S.C. 552a. In accordance with 32 CFR Part 701, subpart E, publication of a general notice of a proposed rule-making concerning exemptions for systems of records is required to appear in the FEDERAL REGISTER at least 30 days prior to the effective date, in order to afford interested persons an opportunity to comment. 32 CFR 701, subpart G indicates systems so designated, the type of exemption, the authority and reasons for the exemption, and the provisions of 5 U.S.C. 552a from which each system has been exempted.

(b) *Subsection (j)(2) exemptions.* To be eligible for an exemption under the authority of subsection (j)(2), 5 U.S.C. 552a requires that a system of records be maintained by an activity whose principal function involves the enforcement of criminal laws, and that the system consist of criminal identifying data, criminal investigative records, or reports concerning an individual at any stage of the law enforcement process, from indictment or referral of charges to release from supervision.

(1) By perfecting a subsection (j)(2) exemption, a system of records may be exempted from one or more of the following provisions of 5 U.S.C. 552a as specified in the published rule pertaining to the system: Subsections (a)(3) and (4), (d), (e)(1) through (3), (e)(4)(G) through (I), (e)(5), (e)(8), (f), and (g).

(2) These cited subsections include the requirements for providing individuals with opportunity to obtain notification, access, and amendment concerning their records, the requirement for providing individuals with disclosure accountings and notification concerning disclosures pursuant to court orders, the requirement for providing individuals with Privacy Act statements, the requirement for collecting personal information directly from the individuals concerned, and the provisions allowing individuals to seek civil remedies aginst the Department.

(c) *Subsection (k) exemptions.* Exemptions under the authority of subsection (k) of 5 U.S.C. 552a differ from those under subsection (j)(2). While broader categories of systems are eligible for exemption under subsection (k), the effect of a subsection (k) exemption is more limited in scope than is a subsection (j)(2) exemption. Subsection (k) exemptions apply only to eligible records in designated systems, and may exempt the eligible records only from one or more of the following provisions of 5 U.S.C. 552a: subsections (c)(3), (d), (e)(1), (e)(4)(G) through (I), and (f). These subsections include the requirements for providing individuals with opportunity to obtain notification, access, and amendment concerning their records, and the requirement for providing individuals with accountings of disclosures. To be eligible for a subsection (k) exemption, the pertinent records within a designated system must contain one or more of the following:

(1) Information specifically authorized to be classified under OPNAVINST 5510.1E and Executive Order No. 11652; ((k)(1) exemption);

(2) Investigative records compiled for law enforcement purposes, other than material covered under a subsection (j) exemption; ((k)(2) exemption);

(3) Records maintained in connection with providing protective services to the President of the United States or other individuals protected pursuant to 18 U.S.C. 3056; ((k)(3) exemption);

(4) Records used only for statistical, research, or other evaluation purposes, and which are not used to make decisions on the rights, benefits, or privileges of individuals, except as permitted by 13 U.S.C. 8 ((k)(4) exemption);

(5) Confidential source information (see paragraph (e) of this section) in investigative records compiled solely for the purpose of determining suitability, eligibility, or qualifications for Federal civilian employment, military service, Federal contracts, or access to classified information; ((k)(5) exemption);

(6) Test or examination material used solely to determine individual qualifications for appointment or promotion in the Federal service, the disclosure of which would compromise the objectivity or fairness of the testing or examination process; ((k)(6) exemption); or

(7) Confidential source information (see paragraph (e) of this section) in evaluation records used for determining potential for promotion in the armed services ((k)(7) exemption).

(d) *Limitations on denying notification, access, and/or amendment on the basis of an exemption.* (1) *Classified information.*—Prior to denying a request for notification, access, or amendment concerning a classified record on the basis of a subsection (k)(1) exemption, denial authorities having classification jurisdiction over the classified matters in the record shall review the record to determine if the classification is proper under the criteria of OPNAVINST 5510.1E. If the denial authority does not have classification jurisdiction, immediate coordination shall be effected with the official having classification jurisdiction, in order to obtain a review of the propriety of the classification. If it is determined upon review that the classification is proper, consideration shall also be given to the appropriateness of permitting the requester to view the record in classified form, provided that he has or can be given the requisite security clearance.

(2) *Law enforcement records*—Requests for notification or access shall not be denied on the basis of a subsection (k)(2) exemption if the requested record has been used as a basis for denying the individual a right, benefit, or privilege to which he would be entitled in the absence of the record, except that access may be limited to the extent necessary to protect the identity of a confidential source, as defined in paragraph (e) of this section. Additionally, neither a subsection (j)(2) nor a subsection (k)(2) exemption shall be the basis for a denial of a request for notification or access concerning a record, or a portion thereof, unless granting the request is in accordance with the exemptions specified in 5 U.S.C. 552a, and would:

(i) Interfere with enforcement proceedings;

(ii) Deprive a person of a right to a fair trial or an impartial adjudication;

(iii) Constitute an unwarranted invasion of personal privacy;

(iv) Disclose the identity of a confidential source or disclose confidential information furnished only by a confidential source in the course of a criminal investigation or in the course of a lawful national security intelligence investigation;

(v) Disclose investigative techniques and procedures not already in the public domain and requiring protection from public disclosure to ensure their effectiveness;

(vi) Endanger the life or physical safety of law-enforcement personnel; or

(vii) Otherwise be deemed not releasable under 5 U.S.C. 552 and 32 CFR Part 701, subparts A–D.

(e) *Confidential sources.* For the purposes of subsection (k) exemptions, a "confidential source" is a person who has furnished information to the Federal Government under:

(1) An express promise that his identity would be held in confidence, or

(2) An implied promise made prior to September 27, 1975, that his identity would be held in confidence.

(f) *Promises of confidentiality.* Express promises of confidentiality shall be granted on a selective basis, and only when such promises are needed and are in the interest of the service. Officials exercising denial authority shall establish appropriate procedures and standards governing the granting of confidentiality for records systems within their cognizance.

§ 701.112 Contractors.

Any unit, activity, or official letting a contract that involves the maintenance of a system of records to accomplish a Department of the Navy purpose shall include in that contract such terms as are necessary to incorporate the relevant provisions of 5 U.S.C. 552a.

§ 701.117 Rules for amendment requests.

5 U.S.C. 552a provides for individuals to request amendment of their personal records where the individuals believe the records to be inaccurate, irrelevant, untimely, or incomplete. The following rules for amendment requests are in effect:

(a) Requests must be in writing and must indicate that they are being made under the Privacy Act (5 U.S.C. 552a), this subpart, or SECNAVINST 5211.5A. Requests should contain sufficient information to locate and identify the particular record which the requester is seeking to amend (e.g., full name, social security number, date of birth, etc.). A request should also contain a statement of the changes desired to be made to the record, the reasons for requesting amendment, and any available information the requester can provide in support of the request, including pertinent documents and related records.

(b) Requests for amendment must be submitted to the appropriate system manager designated in the published record system notices.

(c) A letter indicating receipt will be sent to the requester within 10 working days after the request has been received by the appropriate system manager. The letter will contain details as to when the requester may expect to be advised of action taken on the request. The requester may also be asked to provide additional verification of his identity. This is to protect the privacy of other individuals by ensuring that the requester is seeking to amend his own records and not, inadvertently or intentionally, the records of another individual.

(d) A letter indicating whether or not the request for amendment has been granted will be sent to the requester as soon as a decision has been reached by the appropriate authority. If it is determined that the requested amendment is warranted, the requester will be advised of the action taken and of the effect of that action. If it is determined that the requested amendment is not warranted, the requester will be advised of the reasons for the refusal and of the procedures and time limits within which the requester can seek further review of the refusal.

§ 701.118 Rules of conduct under the Privacy Act.

(a) *Maintaining personal records.* It is unlawful to maintain systems of records about individuals without prior announcement in the FEDERAL REGISTER. Anyone who does is subject to criminal penalties up to $5,000. Even with such notice, care shall be taken to keep only

such personal information as is necessary to do what law and the President, by executive order, require. The information is to be used only for the purposes described in the FEDERAL REGISTER.

(b) *Disclosure.* Information about an individual shall not be disclosed to any unauthorized individual. Anyone who makes an unauthorized disclosure on purpose may be fined up to $5,000. Every member or employee of the Department of the Navy who maintains records about individuals has an obligation to do his part in protecting personal information from unauthorized disclosure. This subpart describes when disclosures are authorized.

(c) *Individual access.* Every individual, with certain exceptions, has the right to look at any record the Department of the Navy keeps on him, to copy it, and to request to have it corrected if he considers it wrong. The individual attempting to exercise these rights shall be given courteous and considerate assistance.

(d) *Ensuring accuracy.* The Department of the Navy has an obligation to use only accurate, timely, relevant, and complete information when making decisions about individuals. Every member, official, and employee involved in keeping records on individuals shall assist in the discharge of this obligation.

Subpart G—Privacy Act Exemptions

§ 701.120 Purpose.

This subpart contains rules promulgated by the Secretary of the Navy, pursuant to 5 U.S.C. 552a (j) and (k), and § 701.111 of this part, to exempt certain systems of Department of the Navy records from specified provisions of 5 U.S.C. 552a.

§ 701.121 Exemption for classified records.

All systems of records maintained by the Department of the Navy and its components shall be exempt from the requirements of 5 U.S.C. 552a(d) pursuant to 5 U.S.C. 552a(k)(1), to the extent that the system contains any information properly classified under Executive Order 11652 and that is required by Executive Order 11652 to be kept secret in the interest of national defense or foreign policy. This exemption, which may be applicable to parts of all systems of records, is necessary because certain records systems not otherwise specifically designated for exemptions herein may contain isolated items of information that have been properly classified.

§ 701.122 Exemption for security operations activities.

ID—N00011 J03

Sysname: Security Incident System.

Exemption: Portions of this system of records are exempt from the following subsections of 5 U.S.C. 552a: (c)(3), (c)(4), (d), (e)(2), (3), (e)(4) (G) through (I), (e)(5), (e)(8), (f), and (g).

AUTHORITY: 5 U.S.C. 552a(j)(2).

Reasons: Granting individuals access to information collected and maintained by this agency relating to the enforcement of criminal laws could interfere with orderly investigations, with the orderly administration of justice, and possibly enable suspects to avoid detection or apprehension. Disclosure of this information could result in concealment, destruction, or fabrication of evidence, and jeopardize the safety and well being of informants, witnesses and their families, and of law enforcement personnel and their families. Disclosure of this information could also reveal and render ineffectual investigative techniques, sources, and methods used by this component, and could result in the invasion of privacy of individuals only incidentally related to an investigation. The exemption of the individual's right of access to his records, and the reason therefor, necessitate the exemption of this system of records from the requirements of other cited provisions.

§ 701.123 Exemptions for specific Navy record systems.

(a) Office of Civilian Personnel

(1) *ID—N96021—02*

Sysname: Supervisor's Report of Potential to Perform and Reference Check Records System.

Exemption: Portions of this system of records are exempt from the following subsections of 5 U.S.C. 552a: (c)(3), (d), (e)(4) (G) and (H), and (f).

AUTHORITY: 5 U.S.C. 552a(k)(5).

Reasons: Exempted portions of this system contain information considered relevant and necessary to make a determination as to the qualifications, eligibility, or suitability for Federal employment or access to classified information, and that was obtained by providing express or implied promise to the source that his identity would not be revealed to the subject of the record.

(2) *ID—N96021—44A*

Sysname: Navy Central Clearance Group (NCCG) Records.

Exemption: Portions of this system of records are exempt from the following subsections of 5 U.S.C. 552a: (c)(3), (d), (e)(4) (G) and (H), and (f).

AUTHORITY: 5 U.S.C. 552a(k) (1) and (5).

Reasons: Exempted portions of this system contain information considered relevant and necessary to make a determination as to qualifications, eligibility, or suitability for Federal employment, or access to classified information, and that was obtained by providing an express or implied promise to the source that his identity would not be revealed to the subject of the record.

(3) *ID—N96021—44B.*

Sysname: Civilian Personnel Security Files.

Exemption: Portions of this system of records are exempt from the following subsections of 5 U.S.C. 552a: (c)(3), (d), (e)(4) (G) through (I), and (f).

AUTHORITY: 5 U.S.C. 552a(k) (1), (2), and (5).

Reasons: Exempted portions of this system contain information which has been properly classified under Executive Order 11652, and which is required to be kept secret in the interest of national defense or foreign policy. Exempted portions of this system also contain information considered relevant and necessary to make a determination as to qualifications, eligibility, or suitability for Federal employment or access to classified information, and that was obtained by providing an express or implied promise to the source that his identity would not be revealed to the subject of the record. Granting individuals access to certain information compiled for law enforcement purposes in this system of records could interfere with orderly investigations by disclosing the existence of investigations and investigative techniques, and result in the concealment, destruction, or fabrication of evidence.

(b) Bureau of Naval Personnel.

(1) *ID—N00022.81.*

Sysname: Personnel Security Eligibility Information System.

Exemption: Portions of this system of records are exempt from the following subsections of title 5, United States Code, section 552a: (c)(3), (d), (e)(4) (G) through (I), and (f).

AUTHORITY: 5 U.S.C. 552a(k) (1), (2), (5), and (7).

Reasons: Granting individuals access to information collected and maintained in this system of records could interfere with orderly investigations; result in the disclosure of classified material; jeopardize the safety of informants, witnesses, and their families; disclose investigative techniques; and result in the invasion of privacy of individuals only incidentally related to an investigation. Material will be screened to permit access to unclassified information that will not disclose the identity of sources who provided information to the Government under an express or implied promise of confidentiality.

(2) *ID—N00022.82.*

Sysname: Navy Personnel Evaluation System.

Exemption: Portions of this system of records are exempt from the following subsections of 5 U.S.C. 552a: (c)(3), (d), (e)(1), (e)(4) (G) through (I), and (f).

AUTHORITY: 5 U.S.C. 552a(k) (1), (2), (5), and (7).

Reasons: Granting individuals access to information collected and maintained in this system could result in disclosure of classified material, jeopardize the safety of informants and witnesses and their families, and result in the invasion of privacy of individuals only incidentally related to an investigation. Material will be screened to permit access to unclassified material and to information that will not disclose the sources who provided the information under the express or implied promise of confidentiality.

(3) *ID—N00022EQOPPINFOSYS.*

Sysname: Equal Opportunity Information and Support System.

Exemption: Portions of this system of records are exempt from the following subsections of 5 U.S.C. 552a: (c)(3), (d), (e)(4) (G) through (I), and (f).

AUTHORITY: 5 U.S.C. 552a(k) (1) and (5).

Reasons: Granting access to information in this system of records could result in the disclosure of classified material, or reveal the identity of a source who furnished information to the Government under an express or implied promise of confidentiality. Material will be screened to permit access to unclassified material and to information that will not disclose the identity of a confidential source.

(4) *ID—N00022OFFPROMSYS.*

Sysname: Officer Promotion System.

Exemption: Portions of this system of records are exempt from the following subsections of 5 U.S.C. 552a: (c)(3), (d), (e)(1), (e)(4) (G) through (I), and (f).

AUTHORITY: 5 U.S.C. 552a(k) (1), (5), (6), and (7).

Reasons: Granting individuals access to this system of records could result in the disclosure of classified material, or the identification of sources who provided information to the Government under an express or implied promise of confidentiality. Material will be screened to permit access to unclassified material and to information that does not disclose the identity of a confidential source.

(5) *ID—N00022PERSRECSYS.*

Sysname: Navy Personnel Records System.

Exemption: Portions of this system of records are exempt from the following provisions of 5 U.S.C. 552a: (c)(3), (d), (e)(1), (e)(4) (G) through (I), and (f).

AUTHORITY: 5 U.S.C. 552a(k) (1) and (5).

Reasons: Granting individuals access to certain portions of the information collected and maintained in this system of records could result in the unauthorized disclosure of classified material. Material will be screened in order to provide access to unclassified information that does not disclose the identity of a source who provided information under an express or implied promise of confidentiality.

(c) Navy Recruiting Command.

(1) *ID—N66715.20 SAS.*

Sysname: Officer Selection and Appointment System.

Exemption: Portions of this system of records are exempt from the following subsections of 5 U.S.C. 552a: (c)(3), (d), (e)(1), (e)(4)(G) through (I), and (f).

AUTHORITY: 5 U.S.C. 552a(k) (1), (5), (6), and (7).

Reasons: Granting individuals access to portions of this system of records could result in the disclosure of classified material, or the identification of sources who provided information to the Government under an express or implied promise of confidentiality. Material will be screened to permit access to unclassified material or to information that does not disclose the identity of a confidential source.

(2) *ID—N66715.3RESS.*

Sysname: Recruiting Enlisted Selection System.

Exemption: Portions of this system of records are exempt from the following subsections of 5 U.S.C. 552a: (c)(3), (d), (e)(1), (e)(4) (G) through (I), and (f).

AUTHORITY: 5 U.S.C. 552a(k) (1), (5), (6), and (7).

Reasons: Granting individuals access to portions of this system of records could result in the unauthorized disclosure of classified material or the identification of sources who provided information to the Government under an express or implied promise of confidentiality. Material will be screened to permit access to unclassified material or to information that does not disclose the identity of a confidential source.

(d) Naval Security Group Command.

(1) *ID—N00069NSGHG12PAC01.*

Sysname: Naval Security Group Personnel Security/Access Files.

Exemption: Portions of this system of records are exempt from the following subsections of 5 U.S.C. 552a: (c)(3), (d), (e)(1), (e)(4) (G) through (I), and (f).

AUTHORITY: 5 U.S.C. 552a(k) (1) through (5).

Reasons: Exempted portions of this system contain information that has been properly classified under Executive Order 11652, and that is required to be kept secret in the interest of national defense or foreign policy.

Exempted portions of this system also contain information considered relevant and necessary to make a determination as to qualification, eligibility, or suitability for access to classified special intelligence information, and that was obtained by providing an express or implied promise to the source that his identity would not be revealed to the subject of the record.

(e) Naval Investigative Service.

ID—N63285.

Sysname: NIS Investigative Files System.

Exemption: (1) Portions of this system of records are exempt from the following subsections of 5 U.S.C. 552a: (c)(3), (c)(4), (d), (e) (2) and (3), (e)(4) (G) through (I), (e)(5), (e)(8), (f), and (g).

AUTHORITY: (1) 5 U.S.C. 552a(j)(2).

Reasons: (1) Granting individuals access to information collected and maintained by this component relating to the enforcement of criminal laws could interfere with orderly investigations, with the orderly administration of justice, and possibly enable suspects to avoid detection or apprehension. Disclosure of this information could result in the concealment, destruction, or fabrication of evidence and jeopardize the safety and well being of informants, witnesses and their families, and law enforcement personnel and their families. Disclosure of this information could also reveal and render ineffectual investigative techniques, sources, and methods used by this component, and could result in the invasion of the privacy of individuals only incidentally related to an investigation. The exemption of the individual's right of access to his records, and the reasons therefor, necessitate the exemption of this system of records from the requirements of the other cited provisions.

Exemption: (2) Portions of this system of records are exempt from the following subsections of 5 U.S.C. 552a: (c)(3), (d), (e)(1), (e)(4) (G) through (I), and (f).

AUTHORITY: (2) 5 U.S.C. 552a(k) (1) through (5).

Reasons: (2) The release of disclosure accountings would permit the subject of an investigation to obtain valuable information concerning the nature of that investigation, and the information contained, or the identity of witnesses or informants, and would therefore present a serious impediment to law enforcement. In addition, disclosure of the accounting would amount to notice to the individual of the existence of a record. Access to the records contained in this system would inform the subject of the existence of material compiled for law enforcement purposes, the premature release of which could prevent the successful completion of investigation, and lead to the improper influencing of witnesses, the destruction of records, or the fabrication of testimony.

Exempt portions of this system also contain information that has been properly classified under Executive Order 11652, and that is required to be kept secret in the interest of national defense or foreign policy.

Exempt portions of this system also contain information considered relevant and necessary to make a determination as to qualifications, eligibility, or suitability for Federal civilian employment, military service, Federal contracts, or access to classified information, and was obtained by providing an express or implied assurance to the source that his identity would not be revealed to the subject of the record. The notice for this system of records published in the FEDERAL REGISTER sets forth the basic statutory or related authority for maintenance of the system. However, in the course of criminal investigations, cases, and matters, the Naval Investigative Service will occasionally obtain information concerning actual or potential violations of law that are not strictly within its statutory or other authority, or may compile information in the course of an investigation that may not be relevant to a specific prosecution. In the interest of effective law enforcement, it is necessary to retain such information in this system of records, since it can aid in establishing patterns of criminal activity and can provide valuable leads for Federal and other law enforcement agencies.

The categories of sources of records in this system have been published in

the FEDERAL REGISTER in broad generic terms. The identity of specific sources, however, must be withheld in order to protect the confidentiality of the source of criminal and other law enforcement information. This exemption is further necessary to protect the privacy and physical safety of witnesses and informants.

This system of records is exempted from procedures for notice to an individual as to the existence of records pertaining to him dealing with an actual or potential civil or regulatory investigation, because such notice to an individual would be detrimental to the successful conduct and/or completion of an investigation, pending or future. Mere notice of the fact of an investigation could inform the subject or others that their activities are under, or may become the subject of, an investigation. This could enable the subjects to avoid detection, to influence witnesses improperly, to destroy records, or to fabricate testimony.

(f) Naval Intelligence Command.

(1) ID—N00015.L1000

Sysname: Naval Intelligence Management Information System (NIMIS).

Exemption: Portions of this system of records are exempt from the following subsections of 5 U.S.C. 552a: (c)(3), (d), (e)(4)(G), and (H), and (f).

AUTHORITY: 5 U.S.C. 552(k)(1).

Reasons: Exempted portions of this system contained information that has been properly classified under Executive Order 11652 and that is required to be kept secret in the interest of national defense or foreign policy.

(2) ID—N00015.ON153–1A

Sysname: Status of Downed Naval Aviation Personnel, Southeast Asia Operations.

Exemption: Portions of this system of records are exempt from the following subsections of 5 U.S.C. 552a: (c)(3), (d), (e)(1), (e)(4)(G) through (I), and (f).

AUTHORITY: 5 U.S.C. 552a(k)(1).

Reasons: Exempted portions of this system contain information that has been properly classified under Executive Order 11652, and that is required to be kept secret in the interest of national defense or foreign policy.

(3) ID—N00015.OOK1

Sysname: Special Intelligence Personnel Access File.

Exemption: Portions of this system of records are exempt from the following subsections of 5 U.S.C. 552a: (c)(3), (d), (e)(1), (e)(4)(G)through (I), and (f).

AUTHORITY: 5 U.S.C. 552a(k)(1) and (5).

Reasons: Exempted portions of this system contain information that has been properly classified under Executive Order 11652, and that is required to be kept secret in the interest of national defense or foreign policy. Exempted portions of this system also contain information considered relevant and necessary to make a determination as to qualifications, eligibility, or suitability for access to classified information, and was obtained by providing an express or implied promise to the source that his identity would not be revealed to the subject of the record.

(g) Fleet Aviation Specialized Operational Training Group, Pacific Fleet.

(1) ID—N09191 POW DEBRIEFS

Sysname: Summary Debriefs of Former Prisoners of War.

Exemption: Portions of this system of records are exempt from the following subsections of 5 U.S.C. 552a: (c)(3), (d), (e)(1), (e)(4)(G) through (I), and (f).

AUTHORITY: 5 U.S.C. 552a(k)(1).

REASONS: Exempted portions of this system contain information that has been properly classified under Executive Order 11652, and that is required to be kept secret in the interest of national defense or foreign policy.

(h) Naval Material Command.

(1) ID—N00037 CNM (MAT 09G1)

Sysname: Investigatory (Fraud System).

Exemption: Portions of this system of records are exempt from the following subsections of 5 U.S.C. 552a: (c)(3), (d), (e)(1), (e)(4)(G) through (I), and (f).

AUTHORITY: 5 U.S.C. 552a(k)(1), (2), and (5).

Reasons: Exempt portions of this system of records contain information that has been properly classified under Executive Order 11652, and that is required to be kept secret in the interest of national defense or foreign policy. Exempted portions of this system also contain information considered relevant and necessary to make a determination as to qualifications, eligibility, or suitability for Federal employment and Federal contracts, and that was obtained by providing an express or implied promise to the source that his identity would not be revealed to the subject of the record. Granting individuals access to certain information collected and maintained by this component relating to the enforcement of criminal laws could interfere with orderly investigations, with orderly administration of justice, and possibly enable suspects to avoid detection or apprehension. Disclosure of this information could result in the concealment, destruction, or fabrication of evidence, and could also reveal and render ineffectual investigative techniques, sources, and methods used by this component.

(i) Naval Resale System Office.

(1) ID—N00250 IR-PERS-RECORD

Sysname: Industrial Relations Personnel Records.

Exemption: Portions of this system of records are exempt from the following subsections of 5 U.S.C. 552a: (d), (e)(4)(G) and (H), and (f).

AUTHORITY: 5 U.S.C. 552a(k)(5) and (6).

Reasons: Exempted portions of this system contain information considered relevant and necessary to make a determination as to the qualifications, eligibility, or suitability for Federal employment, and was obtained by providing an express or implied promise to the source that his identity would not be revealed to the subject of the record. Exempted portions of this system also contain test or examination material used solely to determine individual qualifications for appointment or promotion in the Federal service, the disclosure of which would compromise the objectivity or fairness of the testing or examination process.

(j) Navy and Marine Corps Exchanges and Commissaries.

(1) ID—N00011J010

Sysname: Navy and Marine Corps Exchange and Commissary Security Files.

Exemption: Portions of this system of records are exempt from the following subsections of 5 U.S.C. 552a: (c)(3), (d), (e)(1), (e)(4)(G) through (I), and (f).

AUTHORITY: 5 U.S.C. 552a(k)(2).

Reasons: Granting individuals access to information collected and maintained by these activities relating to the enforcement of criminal laws could interfere with orderly investigations with the orderly administration of justice, and possibly enable suspects to avoid detection or apprehension. Disclosure of this information could result in the concealment, destruction, or fabrication of evidence, and could also reveal and render ineffectual investigative techniques, sources, and methods used by these activities.

(k) Naval Clemency and Parole Board.

(1) ID—N31708 NC&PB

Sysname: Naval Clemency and Parole Board files.

Exemption: Portions of this system of records are exempt from the following subsections of 5 U.S.C. 552a: (c)(4), (d), (e)(4)(G) and (H), and (f).

AUTHORITY: 5 U.S.C. 552a(j)(2).

Reason: Granting individuals access to records maintained by this Board could interfere with internal processes by which Board personnel are able to formulate decisions and policies with regard to clemency and parole in cases involving naval prisoners and other persons under the jurisdiction of the Board. Material will be screened to permit access to all material except such records or documents as reflect items of opinion, conclusion, or recommendation expressed by individual board members or by the board as a whole. The exemption of the individual's right of access to portions of these records, and the reasons therefor, necessitate the partial exemption of this system of records from the requirements of the other cited provisions.

(l) [Reserved]

§ 701.124 Exemptions for specific Marine Corps record systems.

(a) ID—MMN00001

Sysname: Deserter Inquiry File.

Exemption: Portions of this system of records are exempt from the following

subsections of 5 U.S.C. 552a: (c)(3), (c)(4), (d), (e)(2), (e)(3), (e)(4)(G) through (I), (e)(5), (e)(8), (f), and (g).

AUTHORITY: 5 U.S.C. 552a(j)(2).

Reasons: Granting individuals access to information collected and maintained by this component relating to the enforcement of criminal laws could interfere with orderly administration of justice, and possibly enable suspects to avoid detection or apprehension. Disclosure of this information could result in the concealment, destruction, or fabrication of evidence, and jeopardize the safety and well being of informants, witnesses and their families, and law enforcement personnel and their families. Disclosure of this information could also reveal and render ineffectual investigative techniques, sources, and methods used by this component, and could result in the invasion of the privacy of individuals only incidentally related to an investigation.

The exemption of the individual's right of access to his records, and the reasons therefor, necessitate the exemption of this system of records from the requirements from the other cited provisions.

(b) ID—MMN00024

Sysname: Absentee Processing Files.

Exemption: Portions of this system of records are exempted from the following subsections of 5 U.S.C. 552a: (c)(3), (c)(4), (d), (e)(2) and (3), (e)(4)(G) through (I), (e)(5), (e)(8), (f), and (g).

AUTHORITY: 5 U.S.C. 552a(j)(2).

Reasons: Granting individuals access to information collected and maintained by this component relating to the enforcement of criminal laws could interfere with orderly investigations, with the orderly administration of justice, and possibly enable suspects to avoid detection or apprehension. Disclosure of this information could result in the concealment, destruction, or fabrication of evidence, and jeopardize the safety and well being of informants, witnesses and their families, and law enforcement personnel and their families. Disclosure of this information could also reveal and render ineffectual investigative techniques, sources, and methods used by this component, and could result in the invasion of the privacy of individuals only incidentally related to an investigation.

The exemption of the individual's right of access to his records, and the reasons therefor, necessitate the exemption of this system of records from the requirements of the other cited provisions.

(c) ID—MMN00018

Sysname: Base Security Incident Reporting System.

Exemption: Portions of this system of records are exempt from the following subsections of 5 U.S.C. 552a: (c)(3), (c)(4), (d), (e)(2) and (3), (e)(4)(G) through (I), (e)(5), (e)(8), (f), and (g).

AUTHORITY: 5 U.S.C. 552(a)(j)(2).

Reasons: Granting individuals access to information collected and maintained by these activities relating to the enforcement of criminal laws could interfere with orderly investigations, with the orderly administration of justice, and possibly enable suspects to avoid detection or apprehension. Disclosure of this information could result in the concealment, destruction, or fabrication of evidence, and jeopardize the safety and well-being of informants, witnesses and their families, and law enforcement personnel and their families. Disclosure of this information could also reveal and render ineffectual investigative techniques, sources, and methods used by this component, and could result in the invasion of the privacy of individuals only incidentally related to an investigation.

The exemption of the individual's right of access to his records, and the reasons therefor, necessitate the exemption of this system of records from the requirements of the other cited provisions.

(d) ID—MMN00019

Sysname: Drug/Alcohol Abuse Reporting Program.

Exemption: Portions of this system of records are exempt from the following subsections of 5 U.S.C. 552a: (c)(3), (d), (e)(1), (e)(4)(G) through (I), and (f).

AUTHORITY: 5 U.S.C. 552a(k)(2).

Reasons: Granting individuals access to portions of this system of records relating to the enforcement of criminal laws could interfere with orderly investigations and with the orderly administration of justice. Disclosure of this information could result in the concealment, alteration or destruction of evidence, and jeopardize the safety and well-being of formants, witnesses and their families, and law enforcement personnel and their families. Disclosure of this information could also reveal and render ineffectual investigative techniques, sources, and methods used by this component, and could result in the invasion of the privacy of individuals only incidentally related to an investigation. The exemption of the individual's right of access to portions of the records in this record system, and the reasons therefor, necessitate the exemption of this system of records from the requirements of the other cited provisions.

(e) ID—MMN00022

Sysname: Vehicle Control System.

Exemption: Portions of this system of records are exempt from the following subsections of 5 U.S.C. 552a: (c)(3), (c)(4), (d), (e)(2), (e)(3), (e)(4)(G) through (I), (e)(5), (e)(8)(f), and (g).

AUTHORITY: 5 U.S.C. 552a(j)(2).

Reasons: Granting individuals access to portions of records maintained by these activities relating to the enforcement of criminal laws could interfere with orderly investigations, with the orderly administration of justice, and possibly enable suspects to avoid detection or apprehension. Disclosure of this information could result in the concealment, destruction, or fabrication of evidence, and jeopardize the safety and well-being of informants, witnesses and their families, and law enforcement personnel and their families. Disclosure of this information could also reveal and render ineffectual investigative techniques, sources, and methods used by this component, and could result in the invasion of the privacy of individuals only incidentally related to an investigation.

The exemption of the individual's right of access to portions of these records, and the reasons therefor, necessitate the exemption of this system of records from the requirements of the other cited provisions.

(f) ID—MMN00023

Sysname: Prisoner Records.

Exemption: Portions of this system of records are exempt from the following subsections of 5 U.S.C. 552a: (c)(3), (c)(4), (d), (e)(2), (e)(3), (e)(4) (G) through (I), (e)(5), (e)(8) (f) and (g).

AUTHORITY: 5 U.S.C. 552a(j)(2).

Reasons: Granting individuals access to portions of these records pertaining to or consisting of, but not limited to, disciplinary reports, criminal investigations, and related statements of witnesses, and such other related matter in conjunction with the enforcement of criminal laws, could interfere with orderly investigations, with the orderly administration of justice, and possibly enable suspects to avoid detection or apprehension. Disclosure of this information could result in the concealment, destruction, or fabrication of evidence, and jeopardize the safety and well-being of informants, witnesses and their families, and law enforcement personnel and their families. Disclosure of this information could also reveal and render ineffectual investigative techniques, sources, and methods used by these components and could result in the invasion of the privacy of individuals only incidentally related to an investigation.

The exemption of the individual's right of access to portions of these records, and the reasons therefor, necessitate the exemption of this system of records from the requirements of the other cited provisions.

Dated: November 10, 1976.

JOHN S. JENKINS,
Captain, JAGC, U.S Navy Assistant Judge Advocate General (Civil Law).

[FR Doc.76-33834 Filed 11-16-76;8:45 am]

Title 40—Protection of the Environment

CHAPTER I—ENVIRONMENTAL PROTECTION AGENCY

SUBCHAPTER N—EFFUENT GUIDELINES AND STANDARDS

[FRL 644-1]

PART 439—PHARMACEUTICAL MANUFACTURING POINT SOURCE CATEGORY

Interim Final Rulemaking

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Dated: November 9, 1976.

JOHN QUARLES,
Acting Administrator.

Subpart A—Fermentation Products Subcategory

Sec.

439.10 Applicability; description of the fermentation products subcategory.
439.11 Specialized definitions.
439.12 Effluent limitations and guidelines representing the degree of effluent reduction attainable by the application of the best practicable control technology currently available.

Subpart B—Extraction Products Subcategory

439.20 Applicability; description of the extraction products subcategory.
439.21 Specialized definitions.
439.22 Effluent limitations and guidelines representing the degree of effluent reduction attainable by the application of the best practicable control technology currently available.

Subpart C—Chemical Synthesis Products Subcategory

439.30 Applicability; description of the chemical synthesis products subcategory.
439.31 Specialized definitions.
439.32 Effluent limitations and guidelines representing the degree of effluent reduction attainable by the application of the best practicable control technology currently available.

Subpart D—Mixing/Compounding and Formulation Subcategory

439.40 Applicability; description of the mixing/compounding and formulation subcategory.
439.41 Specialized definitions.
439.42 Effluent limitations and guidelines representing the degree of effluent reduction attainable by the application of the best practicable control technology currently available.

Subpart E—Research Subcategory

Sec.

439.50 Applicability; description of the research subcategory.
439.51 Specialized definitions.
439.52 Effluent limitations and guidelines representing the degree of effluent reduction attainable by the application of the best practicable control technology currently available.

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

Subpart A—Fermentation Products Subcategory

§ 439.10 Applicability; description of the fermentation products subcategory.

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

§ 439.11 Specialized definitions.

For the purpose of this subpart:

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

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

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

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

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

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

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

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

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

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

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

Subpart B—Extraction Products Subcategory

§ 439.20 Applicability; description of the extraction products subcategory.

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

§ 439.21 Specialized definitions.

For the purpose of this subpart:

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

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

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

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

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

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

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

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

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

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

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

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

Subpart C—Chemical Synthesis Products Subcategory

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

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

§ 439.31 Specialized definitions.

For the purpose of this subpart:

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

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

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

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

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

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

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

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

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

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

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

Subpart D—Mixing/Compounding and Formulation Subcategory

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

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

§ 439.41 Specialized definitions.

For the purpose of this subpart:

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

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

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

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

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

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

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

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

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

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

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

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

Subpart E—Research Subcategory

§ 439.50 Applicability; description of the research subcategory.

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

§ 439.51 Specialized definitions.

For the purpose of this subpart:

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

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

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

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

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

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

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

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

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

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

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

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

Appendix A—Legal Authority

Existing Point Sources

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

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

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

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

APPENDIX B—TECHNICAL SUMMARY AND BASIS FOR REGULATIONS

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

(1) GENERAL METHODOLOGY

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

BIOLOGICAL TREATMENT PLANT PERFORMANCE DATA

Plant No.	Subcategory	BOD5 removal (percent)	COD removal (percent)	TSS in effluent (milligrams per liter)	Number of samples
05	DE	99	96	6	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	50
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	187
04	AC	80			350
15	C	80	75	47	2
25	AC	65	23		2

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

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

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

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

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

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

IN-PLANT POLLUTION ABATEMENT

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

HOUSEKEEPING AND GENERAL PRACTICES

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

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

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

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

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

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

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

PROCESS TECHNOLOGY

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

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

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

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

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

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

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

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

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

RECYCLE/REUSE PRACTICES

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

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

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

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

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

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

AT-SOURCE

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

CYANIDE DESTRUCTION

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

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

MERCURY REMOVAL

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

AMMONIA REMOVAL

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

MYCELIA REMOVAL

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

SOLVENT REMOVAL

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

SEWER SEGREGATION

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

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

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

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

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

END-OF-PIPE CONTROL TECHNOLOGY

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

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

BPT COST MODEL

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(vii) Economic and inflationary impact analysis.

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

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

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

Appendix C—Summary of Public Participation

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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