AUTHENTICATED
U.S. GOVERNMENT
INFORMATION
GPO

11–23–93
Vol. 58 No. 224

federal register

Tuesday
November 23, 1993

United States
Government
Printing Office
SUPERINTENDENT
OF DOCUMENTS
Washington, DC 20402

OFFICIAL BUSINESS
Penalty for private use, $300

SECOND CLASS NEWSPAPER

Postage and Fees Paid
U.S. Government Printing Office
(ISSN 0097–6326)

11-23-93
Vol. 58 No. 224
Pages 61797-62032

federal register

Tuesday
November 23, 1993

Briefings on How To Use the Federal Register
For information on briefings in Washington, DC, see announcement on the inside cover of this issue.

FEDERAL REGISTER Published daily, Monday through Friday, (not published on Saturdays, Sundays, or on official holidays), by the Office of the Federal Register, National Archives and Records Administration, Washington, DC 20408, under the Federal Register Act (49 Stat. 500, as amended; 44 U.S.C. Ch. 15) and the regulations of the Administrative Committee of the Federal Register (1 CFR Ch. I). Distribution is made only by the Superintendent of Documents, U.S. Government Printing Office, Washington, DC 20402.

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The seal of the National Archives and Records Administration authenticates this issue of the **Federal Register** as the official serial publication established under the Federal Register Act. 44 U.S.C. 1507 provides that the contents of the **Federal Register** shall be judicially noticed.

The **Federal Register** is published in paper, 24x microfiche format and magnetic tape. The annual subscription price for the **Federal Register** paper edition is $375, or $415 for a combined **Federal Register**, Federal Register Index and List of CFR Sections Affected (LSA) subscription; the microfiche edition of the **Federal Register** including the Federal Register Index and LSA is $353; and magnetic tape is $37,500. Six month subscriptions are available for one-half the annual rate. The charge for individual copies in paper form is $4.50 for each issue, or $4.50 for each group of pages as actually bound; or $1.50 for each issue in microfiche form; or $175.00 per magnetic tape. All prices include regular domestic postage and handling. International customers please add 25% for foreign handling. Remit check or money order, made payable to the Superintendent of Documents, or charge to your GPO Deposit Account, VISA or MasterCard. Mail to: New Orders, Superintendent of Documents, P.O. Box 371954, Pittsburgh, PA 15250–7954.

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THE FEDERAL REGISTER

WHAT IT IS AND HOW TO USE IT

FOR: Any person who uses the Federal Register and Code of Federal Regulations.

WHO: The Office of the Federal Register.

WHAT: Free public briefings (approximately 3 hours) to present:

1. The regulatory process, with a focus on the Federal Register system and the public's role in the development of regulations.
2. The relationship between the Federal Register and Code of Federal Regulations.
3. The important elements of typical Federal Register documents.
4. An introduction to the finding aids of the FR/CFR system.

WHY: To provide the public with access to information necessary to research Federal agency regulations which directly affect them. There will be no discussion of specific agency regulations.

WASHINGTON, DC

(two briefings)

WHEN: November 30 at 9:00 am and 1:30 pm

WHERE: Office of the Federal Register, 7th Floor Conference Room, 800 North Capitol Street NW, Washington, DC (3 blocks north of Union Station Metro)

RESERVATIONS: 202–523–4538

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Presidential Documents

Title 3—

The President

Proclamation 6626 of November 18, 1993

National Children's Day, 1993

By the President of the United States of America

A Proclamation

America's children are at once our most precious national resource and our most weighty responsibility. They represent our future hopes and aspirations. By empowering and supporting America's families today, we can make a more secure world for all Americans tomorrow.

Millions of America's children grow up in stable and loving families. At the same time, an alarmingly high number of our youth do not have the benefit of such security; many grow up hungry, neglected, or abused. Far too many reach adolescence having experienced painful episodes of physical, mental, or emotional mistreatment that have long-lasting effects. For them, the future can be clouded with doubt or despair.

We all must take it upon ourselves to address these problems and to guarantee that children of all families will be given new hope for a better life. We must get back to "being our neighbor's keeper" when it comes to raising children. The plight of our neighborhoods and communities must be rectified and replaced with a positive environment in which to grow and live in safety. Today's children are frightened and worried. We must close the opportunity gap and the responsibility gap because all of the children of America deserve an equal chance.

Parents must make an all-out effort to provide an accepting, caring, and loving atmosphere for their children. Grandparents also have an important role to play, as do other members of the extended family.

This is an issue that all Americans can and should support and promote. By becoming directly involved and assuming personal responsibility, we can strengthen our schools, churches, and communities in ways that will reinforce and enhance the importance of values that the family structure can provide. This is all the more critical as the world becomes an increasingly complex and interrelated place. We must interact in the future with any number of new and emerging nations. In order to do this successfully, we will need the talent, dedication, and best efforts of all of our youth.

Today's children will also be tomorrow's parents. To preserve the American Dream, the fiber of our Nation must be strengthened. By instilling a common purpose and assuring ourselves that children are receiving the best and most comprehensive care possible, we can face the awesome challenges that lie ahead. We can start at the family level to bring our country together, solve problems, and make progress.

So I ask all Americans to reaffirm this Nation's commitment to its children. I appeal specifically to parents to spend quality time each day with their children, to listen to their concerns and dreams, and to guide them well as they make the transition into adolescence and adulthood. We have a right and an obligation to make sure our children can rise as far and as high as their talents and determination will let them.

The Congress, by Senate Joint Resolution 139, has designated the third Sunday in November as "National Children's Day" and has authorized and requested the President to issue a proclamation in observance of this day.

NOW, THEREFORE, I, WILLIAM J. CLINTON, President of the United States of America, do hereby proclaim November 21, 1993, as National Children's Day. On this day and every day, I urge all Americans to express their love, advocacy, and appreciation for their children and all children of the world. I invite Federal officials, State and local governments, and particularly the American family, to join together in observing this day with appropriate ceremonies and activities to honor our Nation's children.

IN WITNESS WHEREOF, I have hereunto set my hand this eighteenth day of November, in the year of our Lord nineteen hundred and ninety-three, and of the Independence of the United States of America the two hundred and eighteenth.

William J. Clinton

[FR Doc. 93-28943
Filed 11-19-93; 4:27 pm]
Billing code 3195-01-P

Presidential Documents

Proclamation 6627 of November 18, 1993

National Military Families Recognition Day, 1993

By the President of the United States of America

A Proclamation

Military families are diverse, strong, resourceful, and patriotic. The men and women who serve our country understand that their families provide essential support and make enormous sacrifices every day. We, as a Nation, must also recognize the unselfish contributions of our military families wherever they may be around the world.

As we go about the routine business of our lives, it is easy to forget the daily hardships, inconveniences, separations, and disruptions that our service men and women and their families endure to protect America. These dedicated individuals will affirm that it is their families who invariably sustain them and warm their hearts. In every city and State and in many countries worldwide, service men and women proudly note that the highlight of their day is that special smile, telephone call, or letter they receive. The military family is the motivational force that continually elevates the spirit of the service member when life's joys and sorrows need to be shared.

The Department of Defense has long recognized that the family unit is an important factor in the overall readiness and well-being of the members of the Armed Forces. Indeed, military families make extraordinary contributions to the entire Nation through their efforts to support and encourage their loved ones.

The Congress, by Senate Joint Resolution 115, has designated November 22, 1993, as "National Military Families Recognition Day" and has authorized and requested the President to issue a proclamation in observance of this day.

NOW, THEREFORE, I, WILLIAM J. CLINTON, President of the United States of America, do hereby proclaim November 22, 1993, as National Military Families Recognition Day. I call upon all Americans to join in honoring military families throughout the world. Finally, I ask Federal, State, and local officials and private organizations to observe this day with appropriate ceremonies and activities.

IN WITNESS WHEREOF, I have hereunto set my hand this eighteenth day of November, in the year of our Lord nineteen hundred and ninety-three, and of the Independence of the United States of America the two hundred and eighteenth.

William J. Clinton

[FR Doc. 93-28944
Filed 11-19-93; 4:30 pm]
Billing code 3195-01-P

Rules and Regulations

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This section of the FEDERAL REGISTER contains regulatory documents having general applicability and legal effect, most of which are keyed to and codified in the Code of Federal Regulations, which is published under 50 titles pursuant to 44 U.S.C. 1510.

The Code of Federal Regulations is sold by the Superintendent of Documents. Prices of new books are listed in the first FEDERAL REGISTER issue of each week.

FEDERAL RESERVE SYSTEM

12 CFR Part 204

[Regulation D; Docket No. R–0816]

Reserve Requirements of Depository Institutions; Reserve Requirement Ratios

AGENCY: Board of Governors of the Federal Reserve System.

ACTION: Final rule.

SUMMARY: The Board is amending Regulation D, Reserve Requirements of Depository Institutions, to increase the amount of transaction accounts subject to a reserve requirement ratio of three percent, as required by section 19(b)(2)(C) of the Federal Reserve Act, from $46.8 million to $51.9 million of net transaction accounts. This adjustment is known as the low reserve tranche adjustment. The Board has increased from $3.8 million to $4.0 million the amount of reservable liabilities of each depository institution that is subject to a reserve requirement of zero percent. This action is required by section 19(b)(11)(B) of the Federal Reserve Act, and the adjustment is known as the reservable liabilities exemption adjustment. The Board is also leaving unchanged at $44.8 million the deposit cutoff level that is used in conjunction with the reservable liabilities exemption amount to determine the frequency of deposit reporting.

DATES: *Effective Date:* December 14, 1993.

Compliance Dates: For depository institutions that report weekly, the low reserve tranche adjustment and the reservable liabilities exemption adjustment will be effective on the reserve computation period that begins Tuesday, December 21, 1993, and on the corresponding reserve maintenance period that begins Thursday, December 23, 1993. For institutions that report quarterly, the low reserve tranche adjustment and the reservable liabilities exemption adjustment will be effective on the reserve computation period that begins Tuesday, December 14, 1993, and on the corresponding reserve maintenance period that begins Thursday, January 13, 1994. For all depository institutions, the deposit cutoff level will be used to screen institutions in the second quarter of 1994 to determine the reporting frequency for the twelve month period that begins in September 1994.

FOR FURTHER INFORMATION CONTACT: Patrick J. McDivitt, Attorney (202/452–3818), Legal Division, or June O'Brien, Economist (202/452–3790), Division of Monetary Affairs, Board of Governors of the Federal Reserve System. For the hearing impaired only, Telecommunications Device for the Deaf (TDD), Dorothea Thompson (202/452–3544), Board of Governors of the Federal Reserve System, 20th and C Streets, NW., Washington, DC 20551.

SUPPLEMENTARY INFORMATION: Section 19(b)(2) of the Federal Reserve Act (12 U.S.C. 461(b)(2)) requires each depository institution to maintain reserves against its transaction accounts and nonpersonal time deposits, as prescribed by Board regulations. The initial reserve requirements imposed under section 19(b)(2) were set at three percent for net transaction accounts of $25 million or less and at 12 percent on net transaction accounts above $25 million for each depository institution. Effective April 2, 1992, the Board lowered the required reserve ratio applicable to transaction account balances exceeding the low reserve tranche from 12 percent to 10 percent. Section 19(b)(2) also provides that, before December 31 of each year, the Board shall issue a regulation adjusting for the next calendar year the total dollar amount of the transaction account tranche against which reserves must be maintained at a ratio of three percent. The adjustment in the tranche is to be 80 percent of the percentage change in net transaction accounts at all depository institutions over the one-year period that ends on the June 30 prior to the adjustment.

Currently, the low reserve tranche on net transaction accounts is $46.8 million. The increase in the net transaction accounts of all depository institutions from June 30, 1992, to June 30, 1993 was 13.5 percent (from $695.4 billion to $789.3 billion). In accordance with section 19(b)(2), the Board is amending Regulation D (12 CFR part 204) to increase the low reserve tranche for transaction account for 1994 by $5.1 million to $51.9 million.

Section 19(b)(11)(A) of the Federal Reserve Act (12 U.S.C. 461(b)(11)(B)) provides that $2 million of reservable liabilities [1] of each depository institution shall be subject to a zero percent reserve requirement. Section 19(b)(11)(A) permits each depository institution, in accordance with the rules and regulations of the Board, to designate the reservable liabilities to which this reserve requirement exemption is to apply. However, if net transaction accounts are designated, only those that would otherwise be subject to a three percent reserve requirement (*i.e.*, net transaction accounts within the low reserve requirement tranche) may be so designated.

Section 19(b)(11)(B) of the Federal Reserve Act provides that, before December 31 of each year, the Board shall issue a regulation adjusting for the next calendar year the dollar amount of reservable liabilities exempt from reserve requirements. Unlike the adjustment for net transaction accounts, which adjustment can result in a decrease as well as an increase, the change in the exemption amount is to be made only if the total reservable liabilities held at all depository institutions increases from one year to the next. The percentage increase in the exemption is to be 80 percent of the increase in total reservable liabilities of all depository institutions as of the year ending June 30. Total reservable liabilities of all depository institutions from June 30, 1992, to June 30, 1993, increased by 7.4 percent (from $1,390.6 billion to $1,493.8 billion). Under section 19(b)(11)(B), the reservable liabilities exemption amount will be increased by $0.2 million. Consequently, the reservable liabilities exemption amount for 1994 will increase to $4.0 million.

The effect of the application of section 19(b) of the Federal Reserve Act to the

[1] Reservable liabilities include transaction accounts, nonpersonal time deposits, and Eurocurrency liabilities as defined in section 19(b)(5) of the Federal Reserve Act. The reserve ratio on nonpersonal time deposits and Eurocurrency liabilities is zero percent.

change in the total net transaction accounts and the change in the total reservable liabilities from June 30, 1992 to June 30, 1993 is to increase the low reserve tranche to $51.9 million, to apply a zero percent reserve requirement on the first $4.0 million of transaction accounts, and to apply a three percent reserve requirement on the remainder of the low reserve tranche.

The tranche adjustment and the reservable liabilities exemption adjustment for weekly reporting institutions will be effective on the reserve computation period beginning Tuesday, December 21, 1993, and on the corresponding reserve maintenance period beginning Thursday, December 23, 1993. For institutions that report quarterly, the tranche adjustment and the reservable liabilities exemption adjustment will be effective on the computation period beginning Tuesday, December 14, 1993, and on the reserve maintenance period beginning Thursday, January 13, 1994. In addition, all institutions currently submitting Form FR 2900 must continue to submit reports to the Federal Reserve under current reporting procedures.

In order to reduce the reporting burden for small institutions, the Board has established a deposit reporting cutoff level to determine deposit reporting frequency. Institutions are screened during the second quarter of each year to determine reporting frequency beginning the following September. In July of 1988 the Board set the cutoff level at $40 million plus an amount equal to 80 percent of the annual rate of increase of total deposits.[2] The current reporting cutoff level is $44.8 million.

From June 30, 1992, to June 30, 1993, total deposits fell 0.02 percent, from $3,794.2 billion to $3,793.5 billion. This results in no change in the deposit cutoff level that determines the frequency of reporting. Consequently, the deposit cutoff level will remain at $44.8 million. Based on the indexation of the reservable liabilities exemption, the cutoff level for total deposits above which reports of deposits must be filed will rise from $3.8 million to $4.0 million. Institutions with total deposits below $4.0 million are excused from reporting if their deposits can be estimated from other data sources. The $44.8 million cutoff level for weekly versus quarterly FR 2900 reporting and for quarterly FR 2910q versus annual FR 2910a reporting, and the $4.0 million level threshold for reporting will be used in the second quarter 1994 deposits report screening process, and the adjustments will be made when the new deposit reporting panels are implemented in September 1994.

All U.S. branches and agencies of foreign banks and all Edge and Agreement Corporations, regardless of size, are required to file weekly the Report of Transaction Accounts, Other Deposits and Vault Cash (FR 2900). All other institutions that have reservable liabilities in excess of the exemption level prescribed by section 19(b)(11) of the Federal Reserve Act (known as "nonexempt institutions") and total deposits at least equal to the deposit cutoff level ($44.8 million) are also required to file weekly the Report of Transaction Accounts, Other Deposits and Vault Cash (FR 2900). However, nonexempt institutions with total deposits less than the deposit cutoff level ($44.8 million), may file the FR 2900 quarterly for the twelve month period starting September 1994. Institutions that obtain funds from non-U.S. sources or that have foreign branches or international banking facilities are required to file the Report of Certain Eurocurrency Transactions (FR 2950/2951) at the same frequency as they file the FR 2900.

Institutions with reservable liabilities at or below the exemption level ($4.0 million) (known as "exempt institutions") must file the Quarterly Report of Selected Deposits, Vault Cash, and Reservable Liabilities (FR 2910q) if their total deposits are not below the deposit cutoff level ($44.8 million). Exempt institutions with total deposits less than the deposit cutoff level but more than the exemption amount must file the Annual Report of Total Deposits and Reservable Liabilities (FR 2910a). Institutions that have total deposits less than the exemption amount ($4.0 million) are not required to file deposit reports if their deposits can be estimated from other data sources.

Finally, the Board may require a depository institution to report on a weekly basis, regardless of the cutoff level, if the institution manipulates its total deposits and other reservable liabilities in order to qualify for quarterly reporting. Similarly, any depository institution that reports quarterly may be required to report weekly and to maintain appropriate reserve balances with its Reserve Bank if, during its computation period, it understates its usual reservable liabilities or it overstates the deductions allowed in computing required reserve balances.

[2] "Total deposits" as used in determining the cutoff level includes not only gross transaction deposits, savings accounts, and time deposits, but also reservable obligations of affiliates, ineligible acceptance liabilities, and net Eurocurrency liabilities.

Notice and Public Participation

The provisions of 5 U.S.C. 553(b) relating to notice and public participation have not been followed in connection with the adoption of these amendments because the amendments involve adjustments prescribed by statute and by an interpretative statement reaffirming the Board's policy concerning reporting practices. The amendments also reduce regulatory burdens on depository institutions. Accordingly, the Board finds good cause for determining, and so determines, that notice and public participation are unnecessary and contrary to the public interest.

The provisions of 5 U.S.C. 553(d) relating to notice of the effective date of a rule have not been followed in connection with the adoption of these amendments because the amendments relieve a restriction on depository institutions, and for this reason there is good cause to determine, and the Board so determines, that such notice is not necessary.

Regulatory Flexibility Act Analysis

Pursuant to section 605(b) of the Regulatory Flexibility Act (Pub. L. 96–354, 5 U.S.C. 601 *et seq.*), the Board certifies that the proposed amendments will not have a significant economic impact on a substantial number of small entities. The proposed amendments reduce certain regulatory burdens for all depository institutions, reduce certain burdens for small depository institutions, and have no particular effect on other small entities.

List of Subjects in 12 CFR Part 204

Banks, banking, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, the Board is amending 12 CFR part 204 as follows:

PART 204—RESERVE REQUIREMENTS OF DEPOSITORY INSTITUTIONS (REGULATION D)

1. The authority citation for part 204 is revised to read as follows:

Authority: 12 U.S.C. 248(a), 248(c), 371a, 461, 601, 611, and 3105.

2. In § 204.9 paragraph (a) is revised to read as follows:

§ 204.9 Reserve requirement ratios.

(a)(1) *Reserve percentages.* The following reserve ratios are prescribed for all depository institutions, Edge and Agreement Corporations, and United States branches and agencies of foreign banks:

Category	Reserve requirement
Net transaction accounts:[1]	
$0 to $51.9 million	3 percent of amount.
Over $51.9 million	$1,437,000 plus 10 percent of amount over $51.9 million.
Nonpersonal time deposits.	0 percent.
Eurocurrency liabilities	0 percent.

[1] Dollar amounts do not reflect the adjustment to be made by the next paragraph.

(2) *Exemption from reserve requirements.* Each depository institution, Edge or agreement corporation, and U.S. branch or agency of a foreign bank is subject to a zero percent reserve requirement on an amount of its transaction accounts subject to the low reserve tranche in paragraph (a)(1) of this section not in excess of $4.0 million determined in accordance with § 204.3(a)(3) of this part.

* * * * *

By order of the Board of Governors of the Federal Reserve System, November 17, 1993.

William W. Wiles,

Secretary of the Board.

[FR Doc. 93-28685 Filed 11-22-93; 8:45 am]

BILLING CODE 6210-01-M

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12 CFR Part 215

[Regulation O; Docket No. R-0800]

Loans to Executive Officers, Directors, and Principal Shareholders of Member Banks

AGENCY: Board of Governors of the Federal Reserve System.

ACTION: Interim rule.

SUMMARY: The Board is extending through February 18, 1994, an interim provision in Regulation O permitting adequately capitalized small banks to raise their limit on aggregate lending to insiders from 100 percent up to 200 percent of unimpaired capital and surplus. The extension will prevent a lapse in the availability of the interim rule while the Board considers comments about it.

EFFECTIVE DATE: November 18, 1993.

FOR FURTHER INFORMATION CONTACT: Gordon Miller, Attorney (202/452-2534), Legal Division; William G. Spaniel, Supervisory Financial Analyst (202/452-3469), or Mark Benton, Senior Financial Analyst (202/452-5205), Division of Banking Supervision and Regulation, Board of Governors of the Federal Reserve System. For the hearing impaired only, Telecommunication Device for the Deaf (TDD), Dorothea Thompson (202/452-3544), Board of Governors of the Federal Reserve System, 20th & C Street, NW., Washington, DC 20551.

SUPPLEMENTARY INFORMATION:

Background

Section 22(h) of the Federal Reserve Act (12 U.S.C. 375b), as amended by section 306 of the Federal Deposit Insurance Corporation Improvement Act of 1991 (FDICIA), imposes an aggregate limit on the amount a bank may lend to its executive officers, directors, and principal shareholders (insiders) and their related interests as a class. In general, the limit is equal to the bank's unimpaired capital and unimpaired surplus. 12 U.S.C. 375b(5); 12 CFR 215.4(d). Section 22(h) also authorizes the Board to set a higher limit for banks with deposits of less than $100 million if the Board determines that the exception is "important to avoid constricting the availability of credit in small communities or to attract directors of such banks." The statute provides that the higher limit for smaller banks may not exceed 200 percent of the bank's unimpaired capital and unimpaired surplus.

Effective May 18, 1992, the Board adopted an interim rule permitting adequately capitalized banks with deposits under $100 million to adopt a higher limit, not to exceed 200 percent of the bank's unimpaired capital and unimpaired surplus. The interim rule was scheduled to expire May 18, 1993. See 57 FR 22420, May 28, 1992. The Board subsequently extended the interim rule for six months, through November 18, 1993, in order to obtain public comments on whether the interim rule should be made permanent, modified, or permitted to expire. See 58 FR 28492, May 14, 1993.

In response to the notice of the extension of the interim rule, the Board received 147 written comments. The large majority of the comments were submitted by small banks subject to the interim rule. The Board also has received comments from state and national banking associations, Federal Reserve Banks, state banking superintendents, bank directors, bank holding companies, and law firms. In addition to written comments, the Board has reviewed the call reports of small banks and received relevant information from other governmental agencies.

The Board is hereby extending the interim rule for three months, through February 18, 1994. The Board finds that it is necessary to extend the interim rule in order to prevent any lapse in its availability while the information described above is considered. For the foregoing reasons, the Board for good cause finds that notice and public comment is impracticable, and that the interim rule should be effective immediately. See 5 U.S.C. 553(b)(B) and 553(d)(3). The effective date of this extension is November 18, 1993. Resolutions adopted by small banks to increase their aggregate lending limits that by their terms expired on May 18, 1993, or will expire on November 18, 1993, will be considered by the Board to remain in effect through February 18, 1994.

Initial Regulatory Flexibility Analysis

The Regulatory Flexibility Act (5 U.S.C. 601-612) requires an agency to publish an initial regulatory flexibility analysis. Two of the requirements of an initial regulatory flexibility analysis (5 U.S.C. 603(b))—a description of the reasons why the action by the agency is being considered and a statement of the objectives of, and legal basis for, the rulemaking—are contained in the supplementary information above.

Another requirement of an initial regulatory flexibility analysis is a description and, where feasible, an estimate of the number of small entities to which the interim rule will apply. The interim rule imposes an additional reporting requirement upon small banks that elect to prepare the board of directors resolution required in order to establish a higher aggregate lending limit for themselves. This resolution, which sets forth the facts and reasoning on which the board of directors bases its action, including the amount of the bank's lending to its insiders as a percentage of the bank's unimpaired capital and unimpaired surplus as of the date of the resolution, must be submitted to the appropriate federal banking agency (as defined in 12 U.S.C. 1813(q)) with a copy to the Board. The rulemaking does not duplicate, overlap, or conflict with other relevant federal rules.

Paperwork Reduction Act

In accordance with the Paperwork Reduction Act of 1980, the interim rule will be reviewed by the Board under authority delegated by the Office of Management and Budget after consideration of the comments received during the public comment period. 44 U.S.C. 3507; 5 CFR 1320.130. The interim rule applies to any adequately capitalized bank with deposits under $100 million that chooses to adopt a higher aggregate lending limit. As of December 31, 1992, 8,643 banks were potentially subject to the interim rule.

During the 18-month period in which the interim rule has been in effect, 48 banks have chosen to adopt this policy, and it is not expected that this number will change significantly over the next three months. For banks that choose to adopt a higher aggregate lending limit, the burden per respondent is estimated to be 0.75 hours. Therefore, the estimated aggregate burden is not deemed to be significant.

List of Subjects in 12 CFR Part 215

Credit, Penalties, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, the Board amends title 12 of the Code of Federal Regulations, part 215, subpart A, as follows:

PART 215—LOANS TO EXECUTIVE OFFICERS, DIRECTORS, AND PRINCIPAL SHAREHOLDERS OF MEMBER BANKS (REGULATION O)

1. The authority citation for part 215 is revised to read as follows:

Authority: 12 U.S.C. 248(i), 375a, 375b), 1817(k), and 1972(2)(G)(ii).

2. Section 215.4 is amended by removing from paragraph (d)(2) introductory text the phrase "18-month period ending November 18, 1993" and adding in its place the phrase "21-month period ending February 18, 1994."

By order of the Board of Governors of the Federal Reserve System, November 17, 1993.

William W. Wiles,

Secretary of the Board.

[FR Doc. 93-28686 Filed 11-22-93; 8:45 am]

BILLING CODE 6210-01-F

DEPARTMENT OF COMMERCE

Economic Development Administration

13 CFR Part 301

[Docket No. 930531-3131]

Establishment and Organization; Description of Organization and Information Collection Requirements Under the Paperwork Reduction Act; OMB Control Numbers

AGENCY: Economic Development Administration (EDA), Commerce.

ACTION: Final rule.

SUMMARY: This rule amends regulations relating to EDA's organization description and information collection requirements under the Paperwork Reduction Act. The purpose of these amendments is to make the regulations consistent with the current Departmental Organization Order and assigned OMB Control Numbers.

DATES: Effective date November 23, 1993.

FOR FURTHER INFORMATION CONTACT: Joseph M. Levine, (202) 482–4687, U.S. Department of Commerce, Herbert C. Hoover Building, 14th and Constitution Avenue, NW., Washington, DC 20230.

SUPPLEMENTARY INFORMATION: EDA is amending subpart C, Description of Organization, 13 CFR 301.31(e) by adding the Federated States of Micronesia and the Marshall Islands to the jurisdiction of the Seattle Regional Office; § 301.32 is amended by removing the Executive Secretariat from the Assistant Secretary's direct oversight; § 301.33 is amended by adding to the duties of the Deputy Assistant Secretary (DAS), those of Equal Employment Officer and other civil rights responsibilities, and by removing the Office of Compliance from the DAS' direct oversight.

Section 301.35 is revised to establish and set forth the obligations and duties of the Deputy Assistant Secretary for Program Support, including the direction and supervision of the Budget, Accounting, Information Systems, Executive Secretariat, Operations Review and Analysis, and Compliance Review Divisions, § 301.36 is removed and § 301.37 is renumbered as § 301.36.

Subpart E, 13 CFR 301.70 is revised to list parts of EDA's regulations subject to the Paperwork Reduction Act, and their current OMB control numbers.

This rule is exempt from all requirements of 5 U.S.C. 553 including notice and opportunity to comment and delayed effective date, because it relates to agency management or personnel.

No other law requires that notice and opportunity for comment be given for this rule.

Since a notice and an opportunity for comment are not required to be given for the rule under section 553 of the APA (5. U.S.C. 553) or any other law, under sections 603(a) and 604(a) of the Regulatory Flexibility Act (5 U.S.C. 601–612), no initial or final Regulatory Flexibility Analysis has to be or will be prepared.

This rule does not contain a collection of information for purposes of the Paperwork Reduction Act (Pub. L. 96–511).

This rule does not contain policies with Federalism implications sufficient to warrant preparation of a Federalism Assessment under Executive Order 12612.

List of Subjects in 13 CFR Part 301

Freedom of information, Organization and functions (Government agencies).

For the reasons set out in the preamble, 13 CFR part 301 is amended as set forth below:

PART 301—ESTABLISHMENT AND ORGANIZATION

1. The authority citation for part 301 is revised to read as follows:

Authority: Section 701, Pub. L. 89–136, 79 Stat. 570 (42 U.S.C. 3211); Department of Commerce Organization Order 10–4, as amended (40 FR 56702, as amended).

2. Section 301.31 is amended by revising paragraph (e) to read as follows:

§ 301.31 Economic Development Administration Regional Offices.

* * * * *

(e) *Seattle.* Seattle, Washington. Serving: Alaska, American Samoa, Arizona, California, Guam, Hawaii, Idaho, Nevada, Oregon, Washington, Northern Mariana Islands, Federated States of Micronesia and the Marshall Islands.

* * * * *

3. Section 301.32 is revised to read as follows:

§ 301.32 Assistant Secretary.

The Assistant Secretary for Economic Development directs the programs and is responsible for the conduct of all activities, including overall direction and coordination of the Regional Offices of EDA, subject to the policies and directives prescribed by the Secretary of Commerce.

4. Section 301.33 is revised to read as follows:

§ 301.33 Deputy Assistant Secretary.

(a) The Deputy Assistant Secretary assists the Assistant Secretary in all matters affecting EDA, serves as Equal Employment Opportunity (EEO) Officer, and performs the duties of the Assistant Secretary during the latter's absence. In serving as EEO Officer, the Deputy Assistant Secretary may either delegate the responsibility or directly resolve discrimination complaints in accordance with the provisions of Title VII of the Civil Rights Act, and administer EDA's Affirmative Action Program. Regional Directors report directly to the Deputy Assistant Secretary.

(b) For EDA programs in their regions, Regional Directors process applications for economic development assistance, and monitor and service approved projects.

5. Section 310.35 is revised to read as follows:

§301.35 Deputy Assistant Secretary for Program Support.

The Deputy Assistant Secretary for Program Support reports to the Assistant Secretary; serves as Internal Control Coordinator for EDA; is responsible for coordinating and evaluating internal management control systems; provides for the full range of administrative services, unless otherwise provided at Departmental level, for EDA Headquarters, and as required, for the Regional Office; evaluates, reports, and makes recommendations on the optimum use of staff, funds and physical assets by EDA; and serves as liaison with the Assistant Secretary for Administration on administrative support matters. In addition, the Deputy Assistant Secretary directs and supervises the activities of the Budget Division, Accounting Division, Information Systems Division, Executive Secretariat, Operations Review and Analysis Division, and Compliance Review Division.

(a) The Budget Division develops and prepares the annual budget for EDA; is responsible for the total financial program of EDA, and for the fiscal aspects of EDA programs entrusted to other Federal agencies; and reviews and monitors a fiscal control system for both program and administrative expenses consistent with the requirements of the Anti-Deficiency Act, which shall include, but not be restricted to apportionments/reapportionments, allotment of funds, operating budgets, employment limitations, and analyses of reports and proposed actions.

(b) The Accounting Division develops and maintains accounting systems and prepares financial reports for internal and external use, according to the needs of management, the requirements of laws or regulations and established policies; provides accounting support for effective control of all funds administered to present accurately the status of the appropriate funds within the requirements of the Anti-Deficiency Act and as required by the program officials; analyzes financial and operating data to ensure that financial and management policies are being followed; and serves as the liaison with the Office of the Secretary and other Federal agencies in all accounting matters.

(c) The Information Systems Division plans, develops, acquires, and coordinates information resources, including the use of automatic data processing, office automation, and data communications systems and equipment by EDA; provides information resources management services, including the conduct of feasibility studies and development of plans for systems and programs and implementation of such plans; develops and maintains a comprehensive information and data base system to meet specified requirements for administrative, planning, operational, program management, and program evaluation purposes; and provides periodic and special summary reports on current operational trends and performance comparisons to planned goals.

(d) The Executive Secretariat develops and conducts a program for the efficient management of all official records of the Office of the Assistant Secretary for Economic Development; develops and administers a control system for the Assistant Secretary's correspondence and project activity; receives all correspondence addressed to the Office of the Assistant Secretary, all letters from Congressional Offices addressed to staff and all mail addressed to the Economic Development Administration; assigns it to the appropriate office for action; reviews, edits, distributes, and dispatches responses to correspondence, projects, and action memoranda to or from the Assistant Secretary; maintains prompt follow-up of replies to ensure that deadlines are met; and maintains correspondence and policy files, and provides a selective reference service to files as requested by EDA officials.

(e) The Operations, Review and Analysis Division provides technical staff support to the Deputy Assistant Secretary for Program Support in the areas of agencywide program and policy planning, development and evaluation; designs and conducts or manages contracts to study and evaluate how well EDA programs and policies are achieving objectives; develops, coordinates, reviews, and implements new policies and the modification or elimination of existing policies; develops and coordinates a continuous agencywide planning system; coordinates, reviews and evaluates EDA vulnerability assessments of its internal controls to ensure conformance with OMB Circular A–123; prepares the Assistant Secretary's annual statement to the Secretary of Commerce; coordinates, reviews, and prepares the official responses to reports of EDA received from the Office of Inspector General, the General Accounting Office, Congressional staff, Department staff and others, as required; prepares and transmits **Federal Register** notices; coordinates the Agency's Management-By-Objectives; coordinates and reviews preparation of the EDA Annual Report; designs and coordinates a system of periodic evaluations of Headquarters and regional offices; maintains the directives system and manages the OMB information collection activities for EDA; and designs and controls official forms.

(f) The Compliance Review Division develops policies and procedures and implements the provisions of:

(1) Section 702 of PWEDA, the Prevention of Unfair Competition.

(i) Performs preliminary reviews and when necessary conducts complete section 702 studies, prepares a written report on demand, capacity, and existing competitive enterprises in sufficient detail to support a definitive opinion as to the eligibility of the proposed project.

(ii) Prepares special industry studies as requested by program managers on an as needed basis.

(2) Title IV, Section 401 of PWEDA—Area Eligibility and Designation and Title IV, Section 402 of PWEDA—Annual Review of Area Eligibility.

(i) Determines initial area eligibility and prepares appropriate notices to the affected communities and interested public officials.

(ii) Recommends areas for designation upon completion of all Overall Economic Development Plan (OEDP) requirements.

(iii) Conducts the annual review of area eligibility and identifies areas no longer statistically eligible for designation.

(3) Environmental Requirements on EDA Assisted Projects.

(i) Coordinates all of EDA's environmental activities.

(ii) Develops, as appropriate, Agency procedures for complying with environmental legislation, regulations, and executive orders.

(iii) Serves as EDA's official under the provisions of the National Environmental Policy Act of 1969 (NEPA), as amended, 42 U.S.C. 4321–4370.

(4) Civil Rights Requirements on EDA Assisted Projects.

(i) Establishes effective systems throughout EDA to obtain and monitor reports regarding the program of equality of opportunity and ensures compliance with Civil Rights Policy Directives, Department and EDA regulations.

(ii) Establishes report requirements to ensure equality of opportunity by participants in economic development programs, conducts on-site inspections, and receives, investigates, and resolves complaints.

(iii) Evaluates EDA experience regarding the equal opportunity program from the project activity viewpoint.

(iv) Establishes uniform equal opportunity standards and procedures to be followed in reviewing EDA projects.

§ 301.36 [Removed]

§ 301.37 [Redesignated as § 301.36]

6. Section 301.36 is removed and § 301.37 is redesignated as § 301.36.

7. Section 301.70 is revised to read as follows:

§ 301.70 OMB control numbers assigned pursuant to the Paperwork Reduction Act.

(a) This table displays control numbers assigned to EDA's information collection requirements by the Office of Management and Budget (OMB) pursuant to the Paperwork Reduction Act of 1980, Pub. L. 96–511. EDA intends that this table comply with the requirements of section 3507(f) of the Paperwork Reduction Act, which requires that agencies display a current control number assigned by the Director of OMB for each agency information collection requirement.

(b) Control Number Table:

13 CFR part or section where identified and described	Current OMB control number
Part 305	0610–0011
Part 306	0610–0010
Part 308	0610–0058
Sec. § 309.2(c)	0610–0082
Sec. § 309.22	0610–0011
	0610–0092
Part 311	0610–0003
	0610–0021
Sec. § 312.5	0610–0011

Dated: November 9, 1993.

Wilbur F. Hawkins,

Acting Assistant Secretary for Economic Development.

[FR Doc. 93–28752 Filed 11–22–93; 8:45 am]

BILLING CODE 3510–24–M

Bureau of Export Administration

15 CFR Part 799

[Docket No. 930775–3304]

Foreign Availability Determination and General License GFW Eligibility for Certain Oil Well Perforators Controlled by ECCN 1C18A.o

AGENCY: Bureau of Export Administration, Commerce.

ACTION: Interim rule and request for comments.

SUMMARY: Under section 5(f) of the Export Administration Act (EAA) and part 791 of the Export Administration Regulations (EAR), the Department of Commerce determined that foreign availability exists for certain oil well perforators. The Department made this determination on October 18, 1993, and clarified it on November 8, 1993, following discussions with other agencies, as provided for in the EAA.

This interim rule removes national security-based validated export license requirements for exports of these oil well perforators to most non-controlled countries (i.e., Country Groups T and V, except the People's Republic of China) by making the oil well perforators eligible for export under General License GFW.

A validated export license continues to be required for exports of these oil well perforators to all destinations in Country Groups Q, W, Y, and Z, and the People's Republic of China. A validated export license also continues to be required to the following non-controlled destinations: Iran, Syria, Country Group S, and the South African military and police.

The United States is submitting to COCOM a proposal to remove validated license requirements for exports of these oil well perforators to controlled destinations, (i.e., Country Groups Q, W, Y, and Z and the People's Republic of China).

This rule is expected to result in a reduction in the number of export license applications that will have to be submitted for oil well perforators controlled by 1C18A.o, thereby reducing the paperwork burden on exporters.

DATES: This rule is effective November 23, 1993. Comments must be received by December 23, 1993.

ADDRESSES: Written comments (six copies) should be sent to Steven C. Goldman, Director, Office of Foreign Availability, Bureau of Export Administration, Department of Commerce, room 1087, Washington, DC 20230.

FOR FURTHER INFORMATION CONTACT: For questions of a technical nature, contact Jeffrey Tripp, Office of Technology and Policy Analysis, Telephone: (202) 482–1309.

For questions on the foreign availability assessment, contact Ronald Rolfe, Foreign Industrial Analyst, Office of Foreign Availability, Bureau of Export Administration, Department of Commerce, Telephone: (202) 482–0074.

SUPPLEMENTARY INFORMATION:

Background

Section 5(f)(3) of the EAA and part 791 of the EAR set forth the procedures and criteria for determining the foreign availability of items controlled for national security reasons. The Secretary of Commerce, or the Secretary's designee, is authorized to determine whether foreign availability exists.

With limited exceptions, the Department of Commerce may not maintain national security controls on exports of an item to countries when the Department determines that items of comparable quality are available, in fact, to such countries from foreign sources in quantities sufficient to render the controls ineffective in achieving their purpose.

On June 21, 1993, the Office of Foreign Availability (OFA) initiated a foreign availability assessment of certain oil well perforators controlled by ECCN 1C18A.o in response to a claim filed pursuant to section 791 of the EAR. The Department published a notice of the initiation of the assessment in the **Federal Register** on July 28, 1993. (58 FR 40407).

On October 18, 1993, the Acting Assistant Secretary, having considered the assessment and other relevant information provided by OFA, determined that foreign availability of certain oil well perforators exists within the meaning of section 5(f) of the EAA and part 791 of the EAR. The Department provided all interested agencies an opportunity to review and comment on the assessment and determination. On November 8, 1993, based on discussions with other agencies, the Acting Assistant Secretary clarified the scope of oil well perforators covered by the foreign availability determination, as provided for in the EAA.

This interim rule implements the foreign availability determination as it applies to most non-controlled countries, (i.e., Country Groups T and V, except the People's Republic of China). Under section 5(f)(8), whenever Commerce removes national security controls from an item for foreign availability reasons, Commerce may not maintain such controls on any similar item whose function, technological approach, performance thresholds, and other attributes that form the basis for such controls do not exceed the technical parameters of the item determined to be available.

As a result of this regulatory action, exports of certain oil well perforators no longer require a validated license for national security reasons to any destination in Country Group T or V (except the People's Republic of China). Subject to the restrictions in § 771.2(c), these oil well perforators may be exported under General License GFW to most destinations in Country Groups T and V. General license GFW is not available for exports to Iran, Syria, the

People's Republic of China or the South African military or police and a validated license continues to be required for exports of all oil well perforators controlled by ECCN 1C18A.o to these destinations. Exporters should also be aware that the Department of the Treasury's Office of Foreign Assets Control maintains an embargo on other destinations, such as Iraq, Haiti, and the Federal Republic of Yugoslavia (Serbia and Montenegro).

The United States originally established General license GFW for commodities described in the Advisory Notes in the Commerce Control List that indicate a likelihood of approval for Country Groups Q, W, and Y. However, the United States also uses GFW for commodities not covered by such Advisory Notes when so indicated in the GFW paragraph under the Requirements heading of an entry.

A validated license continues to be required for national security reasons for exports to all destinations in Country Groups T and V for oil well perforators that are still controlled by 1C18A.o (i.e., that exceed the technical parameters described in this regulation).

A validated license requirement also continues to apply to exports of all oil well perforators controlled by 1C18A.o to all destinations in Country Groups Q, S, W, Y, and Z, and the People's Republic of China. Foreign policy-based validated license requirements remain in effect for exports to Iran or Syria of all oil well perforators controlled by 1C18A.o. All other foreign policy-based validated license requirements also remain in effect.

The United States is submitting to COCOM a proposal for removing national security-based validated license requirements for certain oil well perforators controlled by 1C18A.o. Following multilateral review of this proposal by COCOM, the Department will take appropriate action, consistent with the provisions of section 5(f)(3) of the EAA and § 791.7 of the EAR, to remove national security-based validated license requirements for exports of these perforators to controlled destinations, i.e., Country Groups Q, W, Y, and Z and the People's Republic of China.

Rulemaking Requirements

1. This rule involves collections of information subject to the Paperwork Reduction Act of 1980 (44 U.S.C. 3501 *et seq.*). This collection has been approved by the Office of Management and Budget under control numbers 0694–0005, 0694–0007, and 0694–0010.

2. This rule does not contain policies with Federalism implications sufficient to warrant preparation of a Federalism assessment under Executive Order 12612.

3. Because a notice of proposed rulemaking and an opportunity for public comment are not required to be given for this rule by section 553 of the Administrative Procedure Act (5 U.S.C. 553) or by any other law, under section 3(a) of the Regulatory Flexibility Act (5 U.S.C. 603(a) and 604(a)) no initial or final Regulatory Flexibility Analysis has to be or will be prepared.

4. The provisions of the Administrative Procedure Act, 5 U.S.C. 553, requiring notice of proposed rulemaking, the opportunity for public participation, and a delay in the effective date, are inapplicable because this regulation involves a military or foreign affairs function of the United States. Section 13(b) of the EAA does not require that this rule be published in proposed form because this rule does not impose a new control. Further, no other law requires that a notice of proposed rulemaking and an opportunity for public comment be given for this rule.

However, because of the importance of the issues raised by these regulations, this rule is issued in interim form and comments will be considered in the development of final regulations. Accordingly, the Department encourages interested persons who wish to comment to do so at the earliest possible time to permit the fullest consideration of their views.

The period for submission of comments will close December 23, 1993. The Department will consider all comments received before the close of the comment period in developing final regulations. Comments received after the end of the comment period will be considered if possible, but their consideration cannot be assured. The Department will not accept public comments accompanied by a request that a part or all of the material be treated confidentially because of its business proprietary nature or for any other reason. The Department will return such comments and materials to the person submitting the comments and will not consider them in the development of final regulations. All public comments on these regulations will be a matter of public record and will be available for public inspection and copying. In the interest of accuracy and completeness, the Department requires comments in written form. Oral comments must be followed by written memoranda, which will also be a matter of public record and will be available for public review and copying. Communications from agencies of the United States Government or foreign governments will not be made available for public inspection.

The public record concerning these regulations will be maintained in the Bureau of Export Administration Freedom of Information Records Inspection Facility, room 4525, Department of Commerce, 14th Street and Pennsylvania Avenue NW., Washington, DC 20230. Records in this facility, including written public comments and memoranda summarizing the substance of oral communications, may be inspected and copied in accordance with regulations published in part 4 of title 15 of the Code of Federal Regulations. Information about the inspection and copying of records at the facility may be obtained from Alex Braier, Bureau of Export Administration Freedom of Information Officer, at the above address or by calling (202) 482–5653.

List of Subjects in 15 CFR Part 799

Exports, Reporting and recordkeeping requirements.

Accordingly, part 799 of the Export Administration Regulations (15 CFR parts 730–799) is amended as follows:

PART 799—[AMENDED]

1. The authority citation for 15 CFR part 799 is revised to read as follows:

Authority: Pub. L. 90–351, 82 Stat. 197 (18 U.S.C. 2510 *et seq.*), as amended; sec. 101, Pub. L. 93–153, 87 Stat. 576 (30 U.S.C. 185), as amended; sec. 103, Pub. L. 94–163, 89 Stat. 877 (42 U.S.C. 6212), as amended; secs. 201 and 201(11)(e), Pub. L. 94–258, 90 Stat. 309 (10 U.S.C. 7420 and 7430(e)), as amended; Pub. L. 95–223, 91 Stat. 1626 (50 U.S.C. 1701 *et seq.*); Pub. L. 95–242, 92 Stat. 120 (22 U.S.C. 3201 *et seq.* and 42 U.S.C. 2139a); sec. 208, Pub. L. 95–372, 92 Stat. 668 (43 U.S.C. 1354); Pub. L. 96–72, 93 Stat. 503 (50 U.S.C. App. 2401 *et seq.*), as amended (extended by Pub. L. 103–10, 107 Stat. 40); sec. 125, Pub. L. 99–64, 99 Stat. 156 (46 U.S.C. 466c); E.O. 11912 of April 13, 1976 (41 FR 15825, April 15, 1976); E.O. 12002 of July 7, 1977 (42 FR 35623, July 7, 1977), as amended; E.O. 12058 of May 11, 1978 (43 FR 20947, May 16, 1978; E.O. 12214 of May 2, 1980 (45 FR 29783, May 6, 1980); E.O. 12735 of November 16, 1990 (55 FR 48587, November 20, 1990), as continued by Notice of November 11, 1992 (57 FR 53979, November 13, 1992); E.O. 12867 of September 30, 1993 (58 FR 51743, October 7, 1993; and E.O. 12868 of September 30, 1993 (58 FR 51749, October 7, 1993).

2. In Supplement No. 1 to § 799.1 (the Commerce Control List), Category 1 (Materials), ECCN 1C18A is amended by revising the Requirements section to read as follows:

1C18A Items on the International Munitions List

REQUIREMENTS

Validated License Required: QSTVWYZ.
Unit: Kilograms.
Reason for Control: NS.
GLV: $3,000.
GCT: No.
GFW: Yes for items in the Advisory Note and for oil well perforators in 1C18A.o described as "shaped charges specially designed for oil well operations, utilizing one charge functioning along a single axis, that upon detonation produce a hole, and:

(a) Contain any formulation of RDX, PYX, PETN, HNS, or HMX; and

(b) Have only a uniformly shaped conical liner with an included angle of 90 degrees or less; and

(c) Have a total explosive mass of no more than 90 grams; and

(d) Have a diameter not exceeding three inches."

* * * * *

Dated: November 18, 1993.

Iain S. Baird,

Acting Assistant Secretary for Export Administration.

[FR Doc. 93–28760 Filed 11–22–93; 8:45 am]
BILLING CODE 3510–DT–P

DEPARTMENT OF DEFENSE

Department of the Navy

32 CFR Part 706

Certifications and Exemptions Under the International Regulations for Preventing Collisions at Sea, 1972; Amendment

AGENCY: Department of the Navy, DOD.

ACTION: Final rule.

SUMMARY: The Department of the Navy is amending its certifications and exemptions under the International Regulations for Preventing Collisions at Sea, 1972 (72 COLREGS), to reflect that the Judge Advocate General of the Navy has determined that USS HARTFORD (SSN 768) and USS COLUMBIA (SSN 771) are vessels of the Navy which, due to their special construction and purpose, cannot comply fully with certain provisions of the 72 COLREGS without interfering with their special functions as naval submarines. The intended effect of this rule is to warn mariners in waters where 72 COLREGS apply.

EFFECTIVE DATE: November 4, 1993.

FOR FURTHER INFORMATION CONTACT: Captain R.R. ROSSI, JAGC, U.S. Navy, Admiralty Counsel, Office of the Judge Advocate General, Navy Department, 200 Stovall Street, Alexandria, VA 22332–2400, Telephone number: (703) 325–9744

SUPPLEMENTARY INFORMATION: Pursuant to the authority granted in 33 U.S.C. 1605, the Department of the Navy amends 32 CFR part 706. This amendment provides notice that the Judge Advocate General of the Navy, under authority delegated by the Secretary of the Navy, has certified that USS HARTFORD (SSN 768) and USS COLUMBIA (SSN 771) are vessels of the Navy which, due to their special construction and purpose, cannot comply fully with 72 COLREGS: Rule 21(c), pertaining to the arc of visibility of the sternlight; Annex I, section 2(a)(i), pertaining to the height of the masthead light; Annex I, section 2(k), pertaining to the height and relative positions of the anchor lights; and Annex I, section 3(b), pertaining to the location of the sidelights. Full compliance with the above-mentioned 72 COLREGS provisions would interfere with the special functions and purposes of the vessel. The Judge Advocate General of the Navy has also certified that the aforementioned lights are located in closest possible compliance with the applicable 72 COLREGS requirements.

Notice is also provided to the effect that USS HARTFORD (SSN 768) and USS COLUMBIA (SSN 771) are members of the SSN–688 class of vessels for which certain exemptions, pursuant to 72 COLREGS, Rule 38, have been previously authorized by the Secretary of the Navy. The exemptions pertaining to that class, found in the existing tables of § 706.3, are equally applicable to USS HARTFORD (SSN 768) and USS COLUMBIA (SSN 771).

Moreover, it has been determined, in accordance with 32 CFR parts 296 and 701, that publication of this amendment for public comment prior to adoption is impracticable, unnecessary, and contrary to public interest since it is based on technical findings that the placement of lights on this vessel in a manner differently from that prescribed herein will adversely affect the vessel's ability to perform its military functions.

List of Subjects in 32 CFR Part 706

Marine safety, Navigation (Water), Vessels.

PART 706—[AMENDED]

Accordingly, 32 CFR part 706 is amended as follows:

1. The authority citation for 706 continues to read:

Authority: 33 U.S.C. 1605.

§ 706. 2 [Amended]

2. Table One of § 706.2 is amended by adding the following vessels:

TABLE ONE

Vessel	Number	Distance in meters of forward masthead light below minimum required height. § 2(a)(i), Annex I
* * * * *		
USS HARTFORD	SSN–768	3.5
USS COLUMBIA	SSN–771	3.5

3. Table Three of § 706.2 is amended by adding the following vessels:

TABLE THREE

Vessel	Number	Masthead lights arc of visibility; Rule 21(a)	Side lights arc of visibility; Rule 21(b)	Stern lights arc of visibility; Rule 21(c)	Side lights distance inboard of ship's sides in meters 3(b) Annex 1	Stern light, distance forward of stern in meters; Rule 21(c)	Forward anchor light, height above hull in meters 2(K) Annex 1	Anchor lights relationship of aft light to forward light in meters 2(K) Annex 1
* *	*		*	*		*		*
USS HARTFORD	SSN–768	.....	.....	205	4.2	6.2	3.5	1.7 below.
USS COLUMBIA	SSN–771	.....	.....	205	4.2	6.2	3.5	1.7 below.

Dated: November 4, 1993.

J.E. Dombroski,

CAPT, JAGC, U.S. Navy, Acting Judge Advocate General.

[FR Doc. 93–28637 Filed 11–22–93; 8:45 am]

BILLING CODE 3810–AE–P

32 CFR Part 706

Certifications and Exemptions Under the International Regulations for Preventing Collisions at Sea, 1972; Amendment

AGENCY: Department of the Navy, DOD.

ACTION: Final rule.

SUMMARY: The Department of the Navy is amending its certifications and exemptions under the International Regulations for Preventing Collisions at Sea, 1972 (72 COLREGS), to reflect that the Judge Advocate General of the Navy has determined that USS PORT ROYAL (CG 73) is a vessel of the Navy which, due to its special construction and purpose, cannot comply fully with certain provisions of the 72 COLREGS without interfering with its special functions as a naval cruiser. The intended effect of this rule is to warn mariners in waters where 72 COLREGS apply.

EFFECTIVE DATE: November 4, 1993.

FOR FURTHER INFORMATION CONTACT: Captain R.R. Rossi, JAGC, U.S. Navy, Admiralty Counsel, Office of the Judge Advocate General, Navy Department, 200 Stovall Street, Alexandria, VA 22332–2400, Telephone number: (703) 325–9744.

SUPPLEMENTARY INFORMATION: Pursuant to the authority granted in 33 U.S.C. 1605, the Department of the Navy amends 32 CFR part 706. This amendment provides notice that the Judge Advocate General of the Navy, under authority delegated by the Secretary of the Navy, has certified that USS PORT ROYAL (CG 73) is a vessel of the Navy which, due to its special construction and purpose, cannot comply fully with 72 COLREGS, Annex I, section 3(a), pertaining to the location of the forward masthead light in the forward quarter of the ship, the placement of the after masthead light, and the horizontal distance between the forward and after masthead lights, without interfering with its special functions as a naval cruiser. The Judge Advocate General of the Navy has also certified that the aforementioned lights are located in closest possible compliance with the applicable 72 COLREGS requirements.

Moreover, it has been determined, in accordance with 32 CFR parts 296 and 701, that publication of this amendment for public comment prior to adoption is impracticable, unnecessary, and contrary to public interest since it is based on technical findings that the placement of lights on this vessel in a manner differently from that prescribed herein will adversely affect the vessel's ability to perform its military functions.

List of Subjects in 32 CFR Part 706

Marine safety, Navigation (Water), Vessels.

PART 706—[AMENDED]

Accordingly, 32 CFR part 706 is amended as follows:

1. The authority citation for part 706 continues to read:

Authority: 33 U.S.C. 1605.

§ 706.2 [Amended]

2. Table Five of § 706.2 is amended by adding the following vessel:

TABLE FIVE

Vessel	Number	Masthead lights not over all other lights and obstructions. Anex I, sec. 2(f)	Forward masthead light not in forward quarter of ship. Annex I, sec. 3(a)	After masthead light less than ½ ship's length aft of forward masthead light. Annex I, sec. 3(a)	Percentage horizontal separation attained
* * *	*	*	*	*	*
USS PORT ROYAL	CG 73	N/A	X	X	38

Dated: November 4, 1993.

J.E. Dombroski,

CAPT, JAGC, U.S. Navy, Acting Judge Advocate General.

[FR Doc. 93–28639 Filed 11–22–93; 8:45]

BILLING CODE 3810–AE–P

32 CFR Part 706

Certifications and Exemptions Under the International Regulations for Preventing Collisions at Sea, 1972; Amendment

AGENCY: Department of the Navy, DOD.

ACTION: Final rule.

SUMMARY: The Department of the Navy is amending its certifications and exemptions under the International Regulations for Preventing Collisions at Sea, 1972 (72 COLREGS), to reflect that the Judge Advocate General of the Navy has determined that USS SANTA FE (SSN 763) is a vessel of the Navy which, due to its special construction and purpose, cannot comply fully with certain provisions of the 72 COLREGS without interfering with its special functions as a naval submarine. The intended effect of this rule is to warn mariners in waters where 72 COLREGS apply.

EFFECTIVE DATE: November 4, 1993.

FOR FURTHER INFORMATION CONTACT: Captain R.R. Rossi, JAGC, U.S. Navy, Admiralty Counsel, Office of the Judge Advocate General, Navy Department, 200 Stovall Street, Alexandria, VA 22332–2400, Telephone number: (703) 325–9744.

SUPPLEMENTARY INFORMATION: Pursuant to the authority granted in 33 U.S.C. 1605, the Department of the Navy amends 32 CFR part 706. This amendment provides notice that the Judge Advocate General of the Navy, under authority delegated by the Secretary of the Navy, has certified that USS SANTA FE (SSN 763) is a vessel of the Navy which, due to its special construction and purpose, cannot comply fully with 72 COLREGS: Rule 21(c), pertaining to the arc of visibility of the sternlight; Annex I, section 2(a)(i), pertaining to the height of the masthead light; Annex I, section 2(k), pertaining to the height and relative positions of the anchor lights; and Annex I, section 3(b), pertaining to the location of the sidelights. Full compliance with the above-mentioned 72 COLREGS provisions would interfere with the special functions and purposes of the vessel. The Judge Advocate General of the Navy has also certified that the aforementioned lights are located in

closest possible compliance with the applicable 72 COLREGS requirements.

Notice is also provided to the effect that USS SANTA FE (SSN 763) is a member of the SSN–688 class of vessels for which certain exemptions, pursuant to 72 COLREGS, Rule 38, have been previously authorized by the Secretary of the Navy. The exemptions pertaining to that class, found in the existing tables of § 706.3, are equally applicable to USS SANTA FE (SSN 763).

Moreover, it has been determined, in accordance with 32 CFR parts 296 and 701, that publication of this amendment for public comment prior to adoption is impracticable, unnecessary, and contrary to public interest since it is based on technical findings that the placement of lights on this vessel in a manner differently from that prescribed herein will adversely affect the vessel's ability to perform its military functions.

List of Subjects in 32 CFR Part 706

Marine Safety, Navigation (Water), Vessels.

PART 706—[AMENDED]

Accordingly, 32 CFR part 706 is amended as follows:

1. The authority citation for 32 CFR part 706 continues to read:

Authority: 33 U.S.C. 1605.

§ 706.2 [Amended]

2. Table One of § 706.2 is amended by adding the following vessel:

TABLE ONE

Vessel	Number	Distance in meters of forward masthead light below minimum required height. § 2(a)(i), Annex I
* * * * *		
USS SANTA FE	SSN–763	3.5

3. Table Three of § 706.2 is amended by adding the following vessel:

TABLE THREE

Vessel	Number	Masthead lights arc of visibility; Rule 21(a)	Side lights arc of visibility; Rule 21(b)	Stern light arc of visibility; Rule 21(c)	Side lights distance inboard of ship's sides in meters 3(b) Annex 1	Stern light, distance forward of stern in meters; Rule 21(c)	Forward anchor light, height above hull in meters; 2(K) Annex 1	Anchor lights relationship of aft light to forward light in meters 2(K) Annex 1
* *	*		*	*		*		*
USS SANTA FE	SSN–763	.....	.....	205	4.2	6.2	3.5	1.7 below.

Dated November 4, 1993.

J.E. Dombroski,

CAPT, JAGC, U.S. Navy, Acting Judge Advocate General.

[FR Doc. 93–28641 Filed 11–22–93; 8:45 am]

BILLING CODE 3810–AE–P

DEPARTMENT OF AGRICULTURE

Forest Service

36 CFR Part 242

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

50 CFR Part 100

RIN 1018–AB43

Subsistence Management Regulations for Federal Public Lands in Alaska, Subpart D—1993–1994 Subsistence Taking of Fish and Wildlife Regulations; Correction

AGENCY: Forest Service, USDA; Fish and Wildlife Service, Interior.

ACTION: Correcting amendments to final rule.

SUMMARY: This document contains corrections to the final Subsistence Management Regulations for Federal Public Lands in Alaska, Subpart D—1993–1994 Subsistence Taking of Fish and Wildlife, which was published in the **Federal Register** on June 1, 1993 (58 FR 31252–31295). Changes in this document are made to correct errors and omissions in the original subpart D publication.

EFFECTIVE DATE: July 1, 1993.

FOR FURTHER INFORMATION CONTACT: Chair, Federal Subsistence Board, c/o Richard S. Pospahala, Office of Subsistence Management, U.S. Fish and Wildlife Service, 1011 E. Tudor Road, Anchorage, Alaska 99503; telephone (907) 786–3447. For questions specific to National Forest System lands, contact Norman R. Howse, Assistant Director—Subsistence, USDA, Forest Service, Alaska Region, P.O. Box 21628, Juneau, Alaska 99802–1628, telephone (907) 586–8890.

SUPPLEMENTARY INFORMATION: The 1993–1994 subpart D final regulations contain errors and omissions which require correction to maintain certain subsistence taking opportunities. The corrections are made in identical fashion at 36 CFR part 242 and 50 CFR part 100.

The Federal Subsistence Board (Board) finds these corrections to be exempt from Administrative Procedures Act (APA) requirements for public notice and public comments prior to publication. In this instance, the Board finds that such requirements are impracticable, unnecessary, and contrary to public interest. Corrections contained herein accurately reflect actions previously taken by the Board under full public review processes. Public notice and public comment opportunities on issues underlying these corrections were formerly afforded through the **Federal Register**, newspaper publications, public meetings, and other means. Further notice and public comment on these corrections would impede the regulatory process, would provide insignificant benefits in nature and impact, would unnecessarily restrict certain subsistence opportunities, and would generally fail to serve overall public interest. Therefore, the Board has not reapplied notice and public comment procedures prior to publication of these corrections.

The Board also finds good cause to implement these corrections as of July 1, 1993, the date on which these measures would have taken effect had inadvertent oversights not occurred. Minor errors in editing constitute the only reason that these provisions were omitted from the final rule published on June 1, 1993 (58 FR 31252–31295). The Board therefore

finds these corrections to be exempt from APA requirements for publication 30 days prior to the effective date.

List of Subjects

36 CFR Part 242

Administrative practice and procedure, Alaska, Fish, National forests, Public lands, Reporting and recordkeeping requirements, Wildlife.

50 CFR Part 100

Administrative practice and procedure, Alaska, Fish, Public lands, Reporting and recordkeeping requirements, Wildlife.

For reasons set forth in the preamble, 36 CFR part 242 and 50 CFR part 100 are corrected by making the following correcting amendments:

36 CFR PART 242—[AMENDED]

50 CFR PART 100—[AMENDED]

1. The authority: citation for both 36 CFR part 242 and 50 CFR part 100 continues to read as follows:

Authority: 16 U.S.C. 3, 472, 551, 668dd, 3101–3126; 18 U.S.C. 3551–3566; 43 U.S.C. 1733.

2. Section _____.25 is amended by revising paragraphs (b)(2)(i) introductory text, (b)(2)(iv) introductory text and (f) to read as follows:

§_____.25 Subsistence taking of wildlife.

* * * * *

(b) * * *

(2) * * *

(i) Using a firearm other than a rifle, shotgun, muzzle-loaded rifle, or rifle or pistol using center-firing cartridges, for the taking of ungulates or bears except that—

* * * * *

(iv) Using bait for taking ungulates, bear, wolf, or wolverine; except, that an individual in possession of a valid trapping license may use bait to take wolves and wolverine, and, black bears may be taken with the use of bait in Units 14(A) between April 15–May 25; in Unit 14(B) between April 15–May 31; in Units 1(A)(B)(D), 2, 3, 5, 6, 7 (except Resurrection Creek and its tributaries), 11, 13 and 16 (except Denali State Park), 15 and 17, between April 15–June 15; and in Units 12, 19–21, 24, and 25, between April 15–June 30—

* * * * *

(f) Sealing of marten, lynx, beaver, otter, wolf, and wolverine. No person may possess or transport from Alaska the untanned skin of a marten taken in Units 1–5, 7, 13(E), and 14–16, or the untanned skin of a lynx, beaver, otter, wolf, or wolverine whether taken inside or outside the State, unless the skin has been sealed by an authorized representative of ADF&G in accordance with State regulations.

* * * * *

3. In addition, in the table at _____.25(m)(1) under the species listing of "GOAT", the entry for Unit 1 (D), is revised to read as follows:

§_____.25 Subsistence taking of wildlife.

m * * *

(1) * * *

Bag limits	Open season
* * * * * * *	
GOAT:	
* * * * * * *	
Unit 1(D)—that portion lying north of the Katzehin River and northeast of the Haines highway—1 goat by State registration permit only..	
Unit 1(D)—that portion lying between Taiya Inlet and River and the White Pass and Yukon Railroad.	No open season.
Remainder of Unit 1(D)—1 goat by state registration permit only	Sept. 15–Oct. 15.
* * * * * * *	

Ronald B. McCoy,

Interim Chair, Federal Subsistence Board.

Michael A. Barton,

Regional Forester, USDA-Forest Service.

[FR Doc. 93–26390 Filed 11–22–93; 8:45 am]

BILLING CODE 4310–55–M

DEPARTMENT OF VETERANS AFFAIRS

38 CFR Part 0

RIN 2900–AG27

Standards of Ethical Conduct and Related Responsibilities

AGENCY: Department of Veterans Affairs.

ACTION: Final rule.

SUMMARY: The Department of Veterans Affairs is amending its regulations governing the conduct of VA employees to remove provisions which have been superseded by recently issued Office of Government Ethics (OGE) regulations which took effect on February 3, 1993, and to revise VA ethics program administrative regulations to conform to current legal requirements and refine VA ethics program responsibilities.

EFFECTIVE DATE: November 23, 1993.

FOR FURTHER INFORMATION CONTACT: Audley Hendricks, Assistant General Counsel (023), Office of the General Counsel, Veterans Administration, 810 Vermont Avenue, NW., Washington, DC 20420, (202) 633–7081.

SUPPLEMENTARY INFORMATION: In 1989, the President issued Executive Order 12674 (later modified by E.O. 12731) directing the Office of Government Ethics (OGE) to "establish a single, comprehensive, and clear set of executive branch standards of conduct that shall be objective, reasonable, and enforceable" and giving OGE authority, with the concurrence of the Attorney General, to issue regulations interpreting 18 U.S.C. 207–209. The order also directed OGE to promulgate regulations establishing a system of confidential financial disclosure by executive branch employees, and to administer the training requirements of the order. Finally, the order required that the Secretary ensure that the Designated Agency Ethics Official's rank, responsibilities, authority, staffing and resources be sufficient to ensure the effectiveness of the VA ethics program.

The Office of Government Ethics, on August 7, 1992, published its final rule establishing Government-wide Standards of Ethical Conduct for Executive Branch Employees. 57 FR 35006. The new regulations, which are codified at 5 CFR part 2635, took effect on February 3, 1993, and, pursuant to the Executive order, have supplanted

most of the VA standards of conduct regulations. 57 FR 35006 (1992).

The Office of Government Ethics, on April 7, 1992, published its final rule establishing executive agency ethics training programs. 57 FR 11886. The new regulations, which are codified at 5 CFR part 2638, took effect May 7, 1992, and required each agency to provide initial ethics orientation to all its employees and annual ethics training for employees in certain sensitive positions 57 FR 11886 (1992).

The Office of Government Ethics, on April 7, 1992, published its interim rule on financial disclosure, including the new branch-wide confidential financial disclosure system. 57 FR 11800. The new regulations, which are codified at 5 CFR part 2634, require VA, *inter alia*, to establish a new confidential financial disclosure system.

The purposes of this rule are to remove those portions of VA's standards of conduct regulations, codified at subparts B and C of 38 CFR part 0, which have been superseded by the Government-wide regulations, and to revise the general provisions in subpart A of part 0 pertaining to the VA ethics program, which have also been affected by the new standards of conduct, the new financial disclosure regulations, and the new training regulations. In this rulemaking document, the VA is revising subpart A, and retaining and renumbering four residual provisions in subpart B which have not been superseded. Also included is a cross-reference to the executive branch-wide Standards of Ethical Conduct at 5 CFR part 2635 and the executive branch-wide financial disclosure regulation at 5 CFR part 2634.

Those regulations in subpart B not being removed will remain in effect for all purposes. There are four provisions in this category. Those four are section 0.735–20(e)(4), "intoxicants and drugs," section 0.735–20(e)(5), "patient abuse," section 0.735–21(e), "safety," and section 0.735–21(f), "furnishing testimony," now being renumbered as sections 0.735–11 and 0.735–12.

Pursuant to 5 CFR 2635.105(c)(3), the Department has obtained the concurrence of OGE in the view that the four provisions in subpart B need not be issued as regulations supplementary to part 2635. None of these provisions is intended to modify or amplify any of the standards in part 2635, and they do not involve the authority conveyed in the Executive orders. They are grounded instead in the general authority of section 501, title 38, United States Code, of the Secretary of Veterans Affairs to prescribe regulations "necessary or appropriate" to carry out the Department's mission. Accordingly, the Department is amending the Authority note at the beginning of part 0 to specify section 501 as well as other general provisions concerning rulemaking authority on the matter of employee conduct.

The VA conduct regulations in subpart C, which provide separate rules for special Government employees, are superseded by the OGE Government-wide standards of conduct. VA is repealing subpart C in its entirety. Following the OGE pattern in part 2635 of including special Government employees within the definition of "employee" in 5 CFR 2635.102(h) and delineating within the specific standards of conduct the few special rules that apply only to special Government employees, VA has also included special Government employees within the definition of "employee" in this rule. This rule contains no provisions that apply only to special Government employees; the VA regulations apply to all VA employees.

In addition to implementing the 1989 Executive order, this rule also gives effect to subpart I of part 2634 of title 5, Code of Federal Regulations, which overrode subpart D of part 0 of title 38, CFR. 57 FR 11800 (1992). Thus, the rule removes VA's superseded confidential financial disclosure regulations in subpart D from part 0.

The revisions to the general provisions in subpart A conform VA ethics program regulations to the new requirements imposed by the Executive Order and the implementing regulations. The revisions also set out the administrative responsibilities which the Secretary has assigned to VA ethics officials. New sections entitled "Agency ethics officials" and "Agency designees" replace the assignment of responsibilities in the repealed section entitled "Interpretation and advisory service" with assignments to ethics officials and agency designees identified by the nomenclature of the current OGE ethics program scheme: the designated agency ethics official (DAEO), deputy ethics officials, and agency designees. A section on ethics education implements the ethics training requirements, and replaces the section entitled "Informing employees." The portions of the section entitled "Interpretation and advisory service" which are not replaced by the new sections on ethics officials and agency designees are replaced by the new section on ethics advice. A new section is added which assigns responsibility within VA for both the public and confidential financial disclosure systems. The definition of "person" was removed as superfluous, because the revised part does not contain the term. The definition of special Government employee is no longer necessary, as it has no particular significance in the amended part and is codified at 18 U.S.C. 202. The introductory section on the purpose of the VA ethics program and the final section on violation of these regulations remain unchanged.

Because the VA is required pursuant to the Executive order to remove superseded provisions of part 0, there remains no justification for subpart D. The repeal of subpart C and portions of subparts A and B is necessary because those provisions were superseded by the new Government-wide standards of conduct, confidential disclosure regulations, and training regulations. Thus VA has no discretion in the matter, and VA finds, pursuant to 5 U.S.C. 553 (b)(B), and (d)(3), that there is good cause not to seek public comment on, or a 30-day delayed effective date for, this rule, as such comment and delayed effectiveness are unnecessary and would serve no purpose.

Because the amendments to subpart A are rules of agency organization, practice, or procedure, and a general statement of policy, a notice of proposed rulemaking is not required. 5 U.S.C. 553(b)(B).

Since a notice of proposed rulemaking is unnecessary and will not be published, these amendments do not come within the term "rule" as defined in, and are not made subject to the requirements of, the Regulatory Flexibility Act. 5 U.S.C. 601(2). Nevertheless, the Secretary hereby certifies that these regulatory amendments will not have a significant economic impact on a substantial number of small entities as they are defined in the Regulatory Flexibility Act, 5 U.S.C. 601–612.

There is no Catalog of Federal Domestic Assistance Program number.

List of Subjects in 38 CFR Part 0

Conflicts of interests, Government employees.

Approved: October 4, 1993.

Jesse Brown,

Secretary of Veterans Affairs.

For the reasons set out in the preamble, 38 CFR part 0 is amended as set forth below:

PART 0—STANDARDS OF ETHICAL CONDUCT AND RELATED RESPONSIBILITIES

1. The authority citation for part 0 is revised to read as follows:

Authority: 5 U.S.C. 301; 38 U.S.C. 501; see sections 201, 301, and 502(a) of E.O. 12674, 54 CFR 15159, 3 CFR, 1989 Comp., p. 215 as modified by E.O. 12731, 55 CFR 42547, 3 CFR, 1990 Comp., p. 306.

2. Subpart A is revised to read as follows:

Subpart A—General Provisions

Sec.

0.735–1 Purpose.
0.735–2 Definitions.
0.735–3 Agency ethics officials.
0.735–4 Agency designees.
0.735–5 Ethics education.
0.735–6 Ethics advice.
0.735–7 Financial disclosure.
0.735–8 Violation of regulations.

Subpart A—General Provisions

§ 0.735–1 Purpose.

For proper performance of the Government business and the maintenance of confidence by citizens in their Government, employees in the Department of Veterans Affairs shall maintain the highest possible standards of honesty, integrity, impartiality, and conduct. They shall avoid misconduct and conflicts of interest through informed judgment as an indispensable means to the maintenance of these high standards.

§ 0.735–2 Definitions.

For the purposes of this part, *employee* means an officer or employee of the Department of Veterans Affairs, including a special Government employee.

§ 0.735–3 Agency ethics officials.

(a) *Designated Agency Ethics Official (DAEO).* The Assistant General Counsel (023) is the designated agency ethics official (DAEO) for the Department of Veterans Affairs. The Deputy Assistant General Counsel (023C) is the alternate DAEO, who is designated to act in the DAEO's absence. The DAEO has primary responsibility for the administration, coordination, and management of the VA ethics program, pursuant to 5 CFR 2638.201–204.

(b) *Deputy ethics officials.* (1) The District Counsel are deputy ethics officials. They have been delegated the authority to act for the DAEO within their jurisdiction, under the DAEO's supervision, pursuant to 5 CFR 2638.204.

(2) The alternate DAEO, the DAEO's staff, and staff in the Offices of District Counsel, may also act as deputy ethics officials pursuant to delegations of one or more of the DAEO's duties from the DAEO or the District Counsel.

§ 0.735–4 Agency designees.

(a)The following officials are "agency designees" for purposes of the standards of conduct in 5 CFR part 2635:

Under Secretaries
Assistant Secretaries
Director, National Cemetery System
General Counsel
Inspector General
Chairman, Board of Veterans Appeals
Chairman, Board of Contract Appeals
Heads of Independent Facilities
Designated Agency Ethics Official
District Counsel.

(b) Agency designees are authorized, pursuant to 5 CFR 2635.102(b), to make specified determinations, grant approval, or take other specified action required or permitted by the standards of conduct with respect to another employee. An agency designee may seek the advice of the DAEO or a deputy ethics official in exercising his or her responsibilities as to any other employee.

§ 0.735–5 Ethics education.

(a) *Initial ethics orientation.* Each new agency employee shall receive initial ethics orientation, pursuant to 5 CFR 2638.703, within 90 days of his or her entrance on duty.

(b) *Annual ethics training.* (1) The following employees shall receive annual ethics training, pursuant to 5 CFR 2638.704:

(i) Employees appointed by the President.

(ii) Employees required to file public financial disclosure reports or confidential financial disclosure reports.

(iii) Officers or employees who have been authorized by the Secretary or his or her designee to enter into, administer, or terminate contracts and make related determinations and findings.

(iv) With respect to any procurement (including the modification or extension of a contract), any civilian or military official or employee of an agency, (including a contractor, subcontractor, consultant, expert, or advisor (other than a competing contractor) acting on behalf of, or providing advice to, the agency with respect to any phase of the agency procurement concerned), who has participated personally and substantially in the drafting of a specification developed for that procurement; the review and approval of a specification developed for that procurement; the preparation or issuance of a procurement solicitation in that procurement; the evaluation of bids or proposals for that procurement; the selection of sources for that procurement; the conduct of negotiations in that procurement; the review and approval of the award, modification, or extension of a contract in that procurement; or such other specific procurement as may be specified in the procurement integrity implementing regulations at 48 CFR 3.104.

(v) Other employees designated by the Secretary or his or her designee based on a determination that such training is desirable in view of their particular duties.

(2) For purposes of administering training, the DAEO, the alternate DAEO, the District Counsel, and attorneys which these individuals designate are "qualified individuals."

(c) *Other ethics education.* The DAEO and deputy ethics officials may conduct such other ethics education, training and orientation for employees as he, she, or they deem(s) appropriate, or as requested by VA management officials.

§ 0.735–6 Ethics advice.

(a) Employees may request and shall receive, upon such request, ethics advice from the DAEO or deputy ethics officials, in accordance with paragraphs (b) and (c) of this section. Former employees may request and shall receive, upon such request, ethics advice related to post-employment restrictions, in accordance with paragraphs (b) and (c) of this section. Employees need not follow the chain of command, and former employees need not follow their former chain of command, in seeking ethics advice from their District Counsel or the DAEO.

(b) The DAEO is authorized to:

(1) Interpret for the Department of Veterans Affairs the laws, executive orders, and regulations relating to employee ethics and conduct matters, and the regulations in this part;

(2) Coordinate counseling services on ethics and conduct matters for employees, and counseling services on post-employment restrictions for former employees;

(3) Resolve questions of conflict of interest, the appearance of conflict of interest and other matters covered in 5 CFR parts 2634, 2635 and this part, whether the questions arise directly from an employee or former employee; or indirectly from an agency designee or a deputy ethics official.

(4) Assure that counseling, advice and interpretations of a precedential nature are available to deputy ethics officials and, if appropriate, other employees, including agency designees;

(c) District Counsel may render advice and interpretations on questions of ethics and conduct matters to any employee, and on questions of post-employment restrictions to former

employees, within the District Counsel's jurisdiction. The District Counsel shall be guided by the interpretations of the DAEO on the pertinent law, executive orders, and regulations. In case of doubt regarding any question, or disagreement of interpretation between District Counsel and employee or former employees, or novel questions of broad application within VA, the District Counsel may submit the matter for consideration by the DAEO.

§ 0.735–7 Financial disclosure.

The DAEO shall administer the public financial disclosure program within the Department of Veterans Affairs. The DAEO shall administer the confidential financial disclosure program, and distribute, collect, review, certify and retain the confidential financial disclosure reports of Central Office employees. The District Counsel shall distribute, collect, review, certify and retain confidential financial disclosure reports for employees whose duty station is within their geographic jurisdiction. The DAEO and District Counsel shall maintain records and reports of the financial disclosure system(s) within their responsibility.

§ 0.735–8 Violation of regulations.

Violation of the regulations in this part by an employee may be cause for appropriate disciplinary action which may be in addition to any penalty prescribed by law.

3. Subpart B is revised to read as follows:

Subpart B—Standards of Ethical Conduct and Related Responsibilities of Employees

Sec.

0.735–10 Cross-reference to employee ethical and other conduct standards and financial disclosure regulations.
0.735–11 Other conduct on the job.
0.735–12 Standards of conduct in special areas.

Subpart B—Standards of Ethical Conduct and Related Responsibilities of Employees

§ 0.735–10 Cross-reference to employee ethical and other conduct standards and financial disclosure regulations.

Employees of the Department of Veterans Affairs (VA) should refer to the executive branch-wide Standards of Ethical Conduct at 5 CFR part 2635, the executive branch-wide Employee Responsibilities and Conduct at 5 CFR part 735, and the executive branch-wide financial disclosure regulation at 5 CFR part 2634.

§ 0.735–11 Other conduct on the job.

Relationship with beneficiaries and claimants. Employees are expected to be helpful to beneficiaries, patients and claimants, but:

(a) An employee shall not procure intoxicants or drugs for, or attempt to sell intoxicants or drugs to, patients or members, or give or attempt to give intoxicants or drugs to them unless officially prescribed for medical use;

(b) An employee shall not abuse patients, members, or other beneficiaries, whether or not provoked.

§ 0.735–12 Standards of conduct in special areas.

(a) *Safety.* (1) Employees will observe safety instructions, signs, and normal safety practices and precautions, including the use of protective clothing and equipment.

(2) An employee shall report each work-connected injury, accident or disease he or she suffers.

(b) *Furnishing testimony.* Employees will furnish information and testify freely and honestly in cases respecting employment and disciplinary matters. Refusal to testify, concealment of material facts, or willfully inaccurate testimony in connection with an investigation or hearing may be ground for disciplinary action. An employee, however, will not be required to give testimony against himself or herself in any matter in which there is indication that he or she may be or is involved in a violation of law wherein there is a possibility of self-incrimination.

Subparts C and D [Removed]

4. Subparts C and D are removed.

[FR Doc. 93–27912 Filed 11–22–93; 8:45 am]
BILLING CODE 8320–01–U

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 799

[OPPTS–42114B; FRL–4648–1]

RIN 2070–AB94

Testing Consent Agreement for N-methylpyrrolidone

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final Consent Agreement.

SUMMARY: EPA has signed an Enforceable Consent Agreement (ECA) pursuant to the Toxic Substances Control Act (TSCA), 15 U.S.C. 2601 *et seq.*, with Arco Chemical Company, BASF Corporation, and International Specialty Products Company, hereinafter, "the Companies" who have agreed to perform certain health effects tests with *n*-methylpyrrolidone (CAS No. 872–50–4) (NMP). This document summarizes the ECA and amends 40 CFR 799.5000 by adding NMP to the list of chemical substances and mixtures subject to ECA's. Accordingly, the export notification requirements of 40 CFR part 707 apply to NMP.

EFFECTIVE DATE: November 23, 1993.

FOR FURTHER INFORMATION CONTACT: Susan B. Hazen, Director, Environmental Assistance Division (7408), Office of Pollution Prevention and Toxics, Rm. E–543B, 401 M St., SW., Washington, DC 20460, (202) 554–1404, TDD (202) 554–0551.

SUPPLEMENTARY INFORMATION: This document amends 40 CFR 799.5000 by adding NMP to the list of chemical substances and mixtures subject to ECAs and export notification requirements.

I. Background

NMP is a possible substitute for methylene chloride for use in paint stripper formulations. Its annual production volume exceeds 55 million pounds. Approximately 2.7 million consumers and more than 71,000 workers may be exposed to NMP.

On March 28, 1990 (55 FR 11398), EPA issued a Notice of Proposed Rulemaking, proposing that NMP manufacturers test NMP for oncogenicity, mutagenicity, developmental and reproductive toxicity, neurotoxicity, and subchronic toxicity. EPA deferred proposing pharmacokinetics testing in the NMP proposed rule because a test guideline for pharmacokinetics was not yet available. The NMP proposed test rule contained a chemical profile of NMP, a discussion of EPA's TSCA section 4(a) findings, and the proposed test standards and reporting requirements.

In addition, in the **Federal Register** of July 15, 1991 (56 FR 32292) EPA reopened the comment period on NMP to permit further comment in relation to EPA's proposed statement of policy for interpreting its legal authority to make TSCA section 4(a)(1)(B) findings.

After EPA issued the Notice of Proposed Rulemaking for NMP, it received data adequate for evaluating the potential mutagenicity and developmental and reproductive toxicity effects of NMP.

On January 29, 1992 EPA's Office of Pollution Prevention and Toxics placed NMP into risk management evaluation after an initial review of the data. On April 15, 1992, EPA informed the NMP manufacturers by letter that it was concerned that there is a potential for adverse health effects on reproduction

and development to persons exposed to NMP. In that letter, EPA also requested additional exposure information, industrial hygiene information, and historical control data not submitted with the reproductive toxicity study.

In response to EPA's April 15, 1992 letter, on May 20, 1992 and June 22, 1992 the manufacturers submitted additional information on use and exposure, glove permeability, on-going testing, and product stewardship.

II. Enforceable Consent Agreement Negotiations

EPA published a **Federal Register** Notice (57 FR 31714; July 17, 1992) announcing an "open season." The "open season" was a time during which manufacturers could submit to EPA proposals for testing chemical substances which had been proposed for testing by EPA but had not been subject to a final test rule. In that notice, EPA indicated that it would review the submissions and select candidates for negotiation of enforceable consent agreements (ECA) pursuant to 40 CFR part 790. EPA also indicated that it would later publish a **Federal Register** notice soliciting persons interested in participating in or monitoring negotiations for the development of consent agreements on the chemicals selected.

On September 11, 1992, the Synthetic Organic Chemical Manufacturers Association (SOCMA) on behalf of "The Companies" submitted a proposal for testing NMP under an ECA. On October 30, 1992, SOCMA sent EPA another letter that added a 2–year oncogenicity bioassay to their testing proposal.

EPA published a **Federal Register** notice (59 FR 16669; March 30, 1993) announcing candidates selected for consent order negotiations and requesting that interested parties identify themselves to EPA. The notice established EPA's priority for initiating negotiations on the chemicals selected, and because the proposal submitted by SOCMA was similar to the testing proposed in EPA's proposed test rule, NMP was among the chemicals assigned a high priority. This **Federal Register** notice also announced a tentative date for starting negotiations on NMP and the other high priority chemicals.

EPA met with identified interested parties, on April 28, 1993 to discuss the testing proposal submitted. EPA conducted subsequent negotiations by letter. Once EPA determined that consensus had been reached it provided a final ECA to the Companies for signature.

The Companies signed the ECA on September 9, 1993, and the Assistant Administrator for EPA's Office of Prevention, Pesticides, and Toxic Substances signed the ECA on November 15, 1993. Because EPA has determined that the data submitted for mutagenicity, developmental, and reproductive toxicity testing required in the proposed test rule is adequate, the final ECA does not require testing for those end points. This ECA is a final action by EPA on NMP; therefore, the NMP proposed test rule will not be adopted as final.

III. Testing Program

The following Table 1 describes the tests, the test standards, and reporting requirements for NMP under the ECA. This testing program will allow EPA to further characterize the potential health hazards resulting from exposure to NMP.

TABLE 1.—REQUIRED TESTING, TEST STANDARDS AND REPORTING REQUIREMENTS FOR NMP

Description of Tests	Test Standard (40 CFR citation)	Deadline for Final Report[1] (Months)	Interim Reports[2] Required Number
Pharmacokinetics; oral, dermal[3], inhalation, and intravenous routes.	795.232 as amended (Appendix I)	15	2
28 day subchronic toxicity range finding study	OECD guideline #407 (adopted in 1981) (Appendix II).	6	0
90 day subchronic toxicity range finding study	798.2650 as amended (Appendix III)	24	3
Functional Observation Battery: subchronic	798.6050 as amended (Appendix IV)	24	3
Motor Activity Test: subchronic	798.6200 as amended (Appendix V)	24	3
Neuropathology: subchronic	798.6400 as amended (Appendix VI)	24	3
Oncogenicity in the mouse and rat administered orally	798.3300 as amended (Appendix VII)	72	12

[1] Number of months after the effective date of the consent order. This reporting requirement includes 19 months for obtaining information from the 28– and 90–day range finding and pharmacokinetics studies.

[2] Interim reports are required every 6 months from the effective date until the final report is submitted. This column shows the number of interim reports required for each test.

[3] The dermal pharmacokinetics consists of a single administration, low dose, dermal exposure group.

IV. Export Notification

The issuance of the ECA subjects any persons who export or intend to export the chemical substance, NMP (CAS No. 872–50–4), of any purity, to the export notification requirements of section 12(b) of TSCA. The listing of the chemical substance at 40 CFR 799.5000 serves as a notification to persons who export or intend to export a chemical substance or mixture that is the subject of an ECA that 40 CFR part 707 applies.

V. Public Record

A. Supporting Documentation

EPA has established a record for this ECA under docket number OPPTS–42114B, which is available for inspection Monday through Friday, excluding legal holidays, in the TSCA Nonconfidential Information Center, East Tower, rm. G–102, 401 M St., SW., Washington, DC 20460 from 8 a.m. to 12 noon and from 1 p.m. to 4 p.m. Information claimed as Confidential Business Information (CBI), while part of the record, is not available for public review. This record contains the basic information considered in developing this Consent Order, and includes the following information:

(1) Testing Consent Agreement for NMP and associated testing protocols attached as appendices.

(2) **Federal Register** notices pertaining to this notice and consent order consisting of:

(a) Notice of Proposed Rulemaking for *N*-methylpyrrolidone, (March 28, 1990, 55 FR 11398)

(b) Notice announcing opportunity to initiate Negotiations for TSCA Section 4

Testing Consent Agreements (July 17, 1992, 57 FR 31714)

(c) Notice announcing Testing Consent Agreement Development for Tier I Chemical Substances; Solicitation for Interested Parties (March 30, 1993, 58 FR 16669)

(3) Communications consisting of:

(a) Written Letters.

(b) Contact reports of telephone summaries.

(c) Meeting summaries.

(4) Reports - published and unpublished factual materials.

VI. Regulatory Assessment Requirements

The Office of Management and Budget (OMB) has approved the information collection requirements contained in the Consent Agreement under the provisions of the Paperwork Reduction Act of 1980, 44 U.S.C. 3501 *et seq.*, and has assigned OMB control 2070–0033.

Public reporting burden for this collection of information is estimated to average 586 hours per response. The estimates include time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.

Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to Chief, Information Policy Branch, 2131, U.S. Environmental Protection Agency, 401 M St., SW., Washington, DC 20460; and to the Office of Management and Budget, Paperwork Reduction Project (2070–0033), Washington, DC 20503.

List of Subjects in 40 CFR Part 799

Environmental protection, Chemicals, Chemical export, Hazardous substances, Health effects, Laboratories, Reporting and recordkeeping requirements, Testing.

Dated: November 15, 1993.

Victor J. Kimm,

Acting Assistant Administrator for Prevention, Pesticides and Toxic Substances.

Therefore, 40 CFR chapter I, part 799 is amended as follows:

PART 799—[AMENDED]

1. The authority citation for part 799 continues to read as follows:

Authority: 15 U.S.C. 2603, 2611, 2625.

2. Section 799.5000 is amended by revising the section heading to read as set forth below and by adding *N*-methylpyrrolidone to the table in CAS Number order, to read as follows:

§ 799.5000 Testing Consent Agreements for Substances and Mixtures with Chemical Abstract Service Registry Numbers.

* * * * *

CAS Number	Substance or mixture name	Testing	FR Publication Date
*	*	*	*
872–50–4	*N*-methylpyrrolidone	Health effects	November 23, 1993
*	*	*	*

[FR Doc. 93–28734 Filed 11–22–93; 8:45 am]
BILLING CODE 6560–50–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

42 CFR Parts 401, 488 and 489

[HSQ–159–F]

RIN 0938–AF17

Medicare Program; Granting and Withdrawal of Deeming Authority to National Accreditation Organizations

AGENCY: Health Care Financing Administration (HCFA), HHS.

ACTION: Final rule.

SUMMARY: This rule implements section 1865(a) of the Social Security Act, as amended by sections 2345 and 2346 of the Deficit Reduction Act of 1984 and section 6019 of the Omnibus Budget Reconciliation Act of 1989. The amendments expand the types of providers and suppliers of services that we may consider to meet conditions of participation or certification, nursing home requirements, or conditions for coverage by virtue of their accreditation by a national accreditation program; these providers and suppliers are also subject to validation surveys. The rule also extends confidentiality to accreditation surveys, other than home health agency surveys, done by accreditation programs in addition to the Joint Commission on Accreditation of Healthcare Organizations, except that we may disclose survey and related information to the extent that such information relates to an enforcement action we take on the basis of accreditation survey findings. The rule also provides for: the release to, and use by, HCFA of all accreditation surveys and other relevant information even if a provider or supplier is not subject to a validation survey; the removing of deemed status of a facility based on a validation survey, an accreditation survey, or other information related to either; and appeal procedures for denied or withdrawn approval.

EFFECTIVE DATE: This rule is effective February 22, 1993. The provisions of this rule also apply as of the effective date to any accreditation organization that previously received approval of deeming authority.

FOR FURTHER INFORMATION CONTACT: Irene Gibson, (410) 966–6768.

SUPPLEMENTARY INFORMATION:

I. Background

In order to participate in the Medicare program, providers and most types of suppliers of health care services (such as hospitals and rural health clinics) must meet requirements specified in the Social Security Act (the Act) and any others specified by the Department of Health and Human Services. These requirements are called conditions of participation for providers, conditions for coverage for suppliers, conditions of certification for rural health clinics (RHCs), or long-term care requirements for skilled nursing facilities (SNFs). Any provider or supplier who does not meet these requirements is considered out of compliance and risks having its participation in the Medicare program terminated or may be subject to other adverse actions.

State health departments or similar agencies under contract with HCFA (in accordance with section 1864 of the Act) survey providers and some types of suppliers to ascertain compliance with the conditions of participation, conditions for coverage, or long term care requirements, and to certify their findings to HCFA. On the basis of these State survey agency certifications, HCFA determines whether the provider or supplier qualifies, or continues to qualify, for participation in the

Medicare program, whether deficiencies exist, and if they have been corrected.

Section 1865(a) of the Act provides that a hospital that is accredited by the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) is deemed to meet, by virtue of that accreditation, the Medicare conditions of participation, except those on utilization review, discharge planning and any requirement promulgated by the Secretary under section 1861(e)(9) that is higher than JCAHO requirements for accreditation unless the Secretary determines that the JCAHO process in these areas is at least equivalent to the standards promulgated by the Secretary. This eliminates the need for State survey agencies to determine routinely whether these "deemed" hospitals comply with the requirements of section 1861(e).

Section 1864(c) of the Act authorizes the Secretary to enter into agreements with the State survey agencies to determine, through validation surveys, whether hospitals participating in Medicare on the basis of JCAHO accreditation are in fact meeting the conditions of participation. In order for a JCAHO accredited hospital to be deemed to meet the Medicare conditions of participation, the hospital must agree, if it is included in a validation survey, to authorize the JCAHO to release (and the JCAHO must release), to HCFA or a designated State agency, on a confidential basis, a copy of the most current JCAHO accreditation survey together with any other information related to the survey (including corrective action plans) that the Secretary requires.

Section 1865(b) provides that if a hospital is found to have significant deficiencies, based on a validation survey or any other information, it will no longer be deemed to meet the Medicare conditions of participation.

Section 1865(a) of the Act, until July 18, 1984, provided that if the Secretary found that accreditation of an institution or agency by the American Osteopathic Association (AOA) or another national accreditation organization provided reasonable assurance that any or all of the conditions of sections 1861(e) (for hospitals), 1861(j) (for skilled nursing facilities), and 1861(o) (for home health agencies (HHAs)), as the case may be, were met, to the extent the Secretary deemed it appropriate, the Secretary could treat the entity as meeting the conditions of participation. On July 18, 1984, legislation expanded the types of entities that could be deemed. (See the section entitled "LEGISLATION", below.) Up to the present, we have not determined that any accreditation organization except AOA (for hospitals) has provided these assurances.

Except for hospitals that are accredited by either the JCAHO or the AOA and HHAs that are accredited by the Community Health Accreditation Program (CHAP), no providers are deemed to meet our conditions of participation, long-term care requirements, or conditions for coverage. That is, although JCAHO accredits many other types of providers, such as SNFs, ambulatory surgical centers (ASCs), and RHCs, no members of these other provider categories have been granted deemed status by virtue of their accreditation by the JCAHO.

Section 1864(c) of the Act authorizes the Secretary to enter into an agreement with the State survey agency to survey JCAHO accredited hospitals, either on a selective-sample basis or in response to a substantial allegation that significant deficiencies exist. In a previous rule, under the authority provided in sections 1865(a) and 1871 of the Act, we extended these surveys to AOA-accredited hospitals in order to provide reasonable assurance that an AOA-accredited hospital meets the requirements of section 1861 of the Act.

Under section 1865(a) of the Act, we may deem as meeting conditions of participation a JCAHO accredited hospital only if the hospital authorizes the JCAHO to release to us, and the JCAHO releases to us, its most current accreditation survey together with any other information directly related to the survey (including corrective action plans) as the Secretary requires. This survey and other information is, in general, confidential. However, the survey and other information may be disclosed by us to the extent that it relates to an enforcement action we have taken.

There is no similar specific statutory statement for requiring entities accredited by another accreditation organization to authorize release of accreditation surveys to us. However, under the general authority of section 1865(a) of the Act, we also have required AOA-accredited hospitals to authorize release of their surveys in order to provide reasonable assurance that all the conditions of section 1861(e) (the statutory definition of "hospital") are met. Until July 18, 1984, other than for JCAHO's accreditation findings, there was no statutory authority to keep any accreditation finding confidential.

Current regulations at 42 CFR 488.5 (53 FR 22850, June 17, 1988) implement the statutory requirements of section 1865 of the Act insofar as JCAHO and AOA are concerned. Section 488.6, which applies to both JCAHO and AOA accredited hospitals, implements Section 1864(c) of the Act. This section discusses the basis for selecting a provider for a validation survey, what the provider must do if selected and the effect if it refuses to cooperate.

II. Legislation

July 18, 1984, the Deficit Reduction Act of 1984 (DEFRA, Pub. L. 98–369) was enacted. Section 2345 of DEFRA amended Section 1865(a) of the Social Security Act to require the Secretary to keep confidential the accreditation survey released to us by any accreditation body for any entity accredited by that body.

Section 2346 of DEFRA also amended Section 1865(a) of the Act. This amendment allows us to find that if the accreditation of the enumerated entities by any national accreditation organization provides reasonable assurance that the conditions of participation or certification (for RHCs), or conditions for coverage, are met for these entities, then we may deem these entities as meeting these conditions. These additional entities are: psychiatric hospitals; ASCs; RHCs; laboratories; hospices; HHAs; SNFs; comprehensive outpatient rehabilitation facilities (CORFs); and clinic, rehabilitation agency, or public health agency providers of outpatient physical therapy (which includes speech pathology services) or occupational therapy services.

Section 411 of the Medicare Catastrophic Coverage Act of 1988 (Pub. L. 100–360) also amended section 1865(a) of the Act. This amendment requires the Secretary to keep confidential the accreditation survey released to us by any accreditation organization for any entity other than a survey with respect to a home health agency.

However, section 6019 of the Omnibus Budget Reconciliation Act of 1989 (OBRA '89) (Pub. L. 101–239), enacted December 19, 1989, further amended section 1865(a) of the Act to allow the Secretary to disclose an accreditation survey and information related to it to the extent the survey and information are related to an enforcement action taken by the Secretary. This provision was effective December 19, 1989. Section 6019 of OBRA '89 also amended section 1865(a), effective June 19, 1990, to require JCAHO-accredited hospitals to authorize the JCAHO to release to the Secretary upon request any other information (in addition to the accreditation survey) directly related to the survey as the Secretary may require (including

corrective action plans), if they are to be deemed to meet the conditions of participation. Also effective June 19, 1990, the JCAHO must release the survey and other information to the Secretary in order for the hospital to be deemed to meet the conditions of participation.

III. Provisions of the Proposed Regulations

On December 14, 1990, we published a proposed rule to implement the legislation (55 FR 51434). Below we discuss the proposed revisions.

1. Confidentiality and Disclosure Provisions

We proposed to revise 42 CFR 401.126(b)(2), which concerns information or records that are not available upon public request. We proposed to extend the confidentiality of accreditation surveys and related information to any national accreditation program recognized by HCFA under Section 1865 of the Act that accredits the specified providers or suppliers other than home health agencies (hospitals; psychiatric hospitals; SNFs; hospices; ASCs; RHCs; CORFs; laboratories; and clinic, rehabilitation agency, or public health agency providers of outpatient physical therapy services, speech pathology services, or occupational therapy services).

We would also simultaneously amend § 401.126(b)(2) and add a paragraph (d) to § 401.133, Availability of official reports on providers of services, State agencies, intermediaries, and carriers under Medicare, to indicate that we will disclose any survey and related information released to us by an accreditation organization to the extent they are related to an enforcement action taken by HCFA and the accreditation survey of any HHA. We would add a paragraph (e) to § 401.133 to show that home health agency surveys are available without regard to reason for disclosure. We would also revise the title of § 401.133 to include suppliers.

We also proposed to revise § 488.5, Effect of JCAHO and AOA accreditation, to show that hospitals accredited by JCAHO or AOA must authorize the release to HCFA of the most current accreditation surveys and any other related information (including corrective action plans) HCFA requires. We would also repeat the provision in revised § 401.126(b)(2) and new § 401.133(d) that accreditation surveys and related information may be disclosed to the extent they relate to an enforcement action taken by HCFA. In addition, the accreditation survey of any HHA can be disclosed. We proposed to state that we may determine, based on a validation survey, the accreditation survey or other related information, that the hospital does not meet Medicare conditions of participation.

2. Expansion of Types of Accredited Entities

We proposed to redesignate § 488.6, Validation survey, as § 488.7 and add a new § 488.6, Other national accreditation programs. This new section would amend the regulations to conform to the statute, which permits HCFA to deem entities other than hospitals to meet the conditions of participation or certification or conditions for coverage, if HCFA finds that a national accreditation organization has provided reasonable assurance that these conditions are met. The accreditation organization would have to provide us with reasonable assurance that the requisite conditions of participation or certification, long-term care requirements or conditions for coverage are met by the entities the accrediting body has accredited.

We proposed to revise the regulations to reflect our current policy of publishing in the **Federal Register** any change in organizations whose specified providers or suppliers may be deemed as meeting conditions of participation or certification or conditions for coverage.

We would include parallel provisions in § 488.5 regarding the release and use of accreditation surveys. That is, we would disclose the accreditation survey of any HHA and the most current accreditation survey and related information on any provider or supplier to the extent they are related to an enforcement action taken by HCFA; the provider or supplier must authorize its accreditation organization to release to us a copy of its most current accreditation survey; and we may determine that a provider or supplier does not meet Medicare conditions based on its accreditation survey or related information.

3. Validation Surveys

We proposed that the redesignated § 488.7, Validation survey, would extend the validation survey to the specified types of providers and suppliers accredited by accreditation organizations other than the JCAHO and AOA.

In § 488.7(a), we would make a distinction between a survey done on the basis of a selective sample and one done on the basis of a substantial allegation of significant deficiencies. The first is comprehensive and addresses all conditions of participation or certification, long-term care requirements, or conditions for coverage; the latter is initially directed solely at the requirements related to the allegation. If the State survey agency substantiates the allegation, and HCFA determines that the provider or supplier is out of compliance with one or more conditions of participation, conditions for coverage, or long-term care requirements, the survey agency would then conduct a complete survey.

Paragraphs (b), (c), (d) and (e) would be revised to substitute "provider or supplier" for "hospital" so that our rules would apply to any approved accreditation organization that accredits providers or suppliers other than hospitals. We would also revise paragraph (b) to extend confidentiality to an accreditation survey of any accredited entity other than a home health agency.

4. Review of Accrediting Bodies

In a new section, § 488.9, Federal review of accreditation organizations, we proposed the standards for evaluating applications for deeming authority. We planned to evaluate an accreditation organization's accreditation requirements to determine whether they are equivalent to ours; the organization's survey process to determine the composition of the survey team, its qualifications and its ability to continue surveyor training; the comparability of survey procedures; the organization's monitoring procedures for providers or suppliers found out of compliance; the ability to provide HCFA with electronic data and reports necessary for effective validation and assessment of the survey process; the adequacy of staff and other resources; and the organization's ability to provide adequate resources for performing required surveys.

We proposed to include in HCFA's review of a national accreditation organization the organization's agreement with HCFA to allow the organization to release the most current accreditation survey to us with any information related to the survey that we may require, including corrective action plans. We also indicated that we would publish a notice in the **Federal Register** to notify the public of any organizations whose accredited, specified types of providers or suppliers are deemed to meet Medicare participation requirements. The notice would describe how the accreditation organization's accreditation program provides reasonable assurance that an entity accredited by the organization meets the Medicare requirements.

In this section, we would also establish the criteria and procedures for removing the deeming authority. At the end of a validation review period, HCFA would identify any accreditation programs for which validation survey results indicate a rate of disparity between certifications of the accreditation organization and those of the State agency validating the accreditations of 20 percent or more. We would also identify validation survey results of accreditation programs that indicate a pattern over 2 years or more of increasing disparity between the certifications of the accreditation organization and those of the State agency. In addition, we would assess the equivalency of the accreditation organization's accreditation requirements compared to our comparable requirements if an accreditation organization proposes to adopt new requirements. An organization must provide written notification to HCFA at least 30 days before the effective date of any proposed changes in its accreditation requirements.

We would provide written notification to an accreditation organization indicating that its approval to be an accreditation organization may be in jeopardy based on documentation identified through the validation review. We would include in the notification a statement concerning the discrepancies found; information explaining our deeming authority review; a description of the procedures the accreditation organization may follow to explain or justify findings made during validation review; and a description of what we may do as a result of the findings from the validation review.

We proposed that if we find an accreditation organization to have a disparity rate of 20 percent or more between its accreditation determinations and the certification determinations of the State survey agency or if we find that validation survey results over a period of two or more years show a pattern of increasing disparity between the certifications of the accreditation organization and certifications of the State agency, we would conduct a deeming authority review. We would reevaluate whether the accreditation organization meets all the criteria we have for initial determinations that an organization's specified providers or suppliers are deemed to meet conditions of participation. We defined "rate of disparity" and included an example in the definitions section, § 488.1.

If we determined, following the deeming authority review, that the organization's requirements were not comparable to ours, we would be able to give the organization a conditional approval of its deeming authority for a probationary period of up to 180 days to adopt comparable requirements. If we determined that the rate of disparity identified during the validation review indicates poor performance, we could (1) give conditional approval of its deeming authority for a period of up to one year, effective 30 days after the determination; (2) require the accreditation organization to release to us any facility-specific data we require for continued monitoring; (3) require the organization to provide us with a survey schedule for the purpose of intermittent onsite monitoring (by HCFA, State surveyors, or both) of the accreditation organization's survey process; and (4) publish in the Medicare Annual Report to Congress the name of any accreditation organization we give a probationary period.

Within 60 days after the conclusion of the probationary period, we would determine whether the organization continued to meet the criteria necessary for its accredited providers or suppliers to be deemed to meet conditions of participation or certification, conditions for coverage, or long-term care requirements and issue an appropriate notice. The determination would be based on any or all of the following:

(1) The evaluation of the most recent validation findings. For an organization to continue to have its providers or suppliers deemed to meet conditions of participation, the evaluation would have to show a significant reduction (from the prior two or more years) in the rate of disparity between the certifications of the State agency and the accreditation organization, and show a disparity rate of less than 20 percent;

(2) The evaluation of facility-specific data, as necessary, as well as other information;

(3) The evaluation of an accreditation body's surveyors in terms of qualifications, ongoing training, composition of survey team, etc.;

(4) The evaluation of survey procedures; and

(5) The evaluation of accreditation requirements.

We proposed that if the accreditation organization made no significant improvements during the probationary period, we would remove recognition of deemed authority, effective 30 days after we provided written notice to the organization that its deeming authority was removed. We would also publish a notice in the **Federal Register** giving the basis for removing the deeming authority from the accreditation organization and providing the reasons the organization's accreditation program no longer meets our requirements.

The regulations would state that the existence of any validation review, deeming authority review, probationary period, or any other action by HCFA does not affect or limit the conducting of any validation survey.

5. Other clarifying revisions.

a. We proposed to revise the definition of "accredited hospital" in § 488.1, Definitions, to "accredited provider or supplier" in order to include other providers and suppliers and to include accreditation programs other than the JCAHO and AOA.

b. We proposed to revise the definition of "substantial allegation" in § 488.1 in order to show that such an allegation may be a complaint from a variety of sources. We would clarify that a complaint need not be formal, be directed to HCFA or the survey agency, or be a result of first-hand experiences.

c. We proposed to add to § 488.1 a definition of "conditions of participation", in order to clarify that the requirements include conditions of certification for RHCs, and a definition of "conditions for coverage". We proposed to also define "Medicare condition" as any condition of participation or for coverage or any long term care requirement, in order to avoid repeating the entire list of possibilities every place it is applicable.

We also proposed to add a definition of "validation review period." The "validation review period" would be the period after the end of a fiscal year during which HCFA conducts a review of the previous year's validation surveys.

d. We proposed to add parts 416 and 485 to the list of applicable conditions of participation or conditions for coverage a provider must meet in order to participate in the Medicare program. These parts contain the conditions for ASCs and CORFs.

e. We would revise redesignated § 488.7(d) to parallel paragraph (c) of that section; i.e., we would add that a provider found out of compliance with Medicare conditions following a full State agency survey may be subject to termination of its provider agreement under § 489.53.

f. We proposed to delete current § 488.6(d)(2) concerning when a significant deficiency will be determined not to exist and revise redesignated § 488.7(b)(3) to clarify the necessity for the State agency to follow-up any flaw serious enough to threaten

the hospital's participation in the Medicare and Medicaid programs.

We would make a conforming change to redesignated § 488.7 by removing paragraph § 488.6(e)(3), which allows a hospital to regain its deemed status if it withdraws a prior refusal to authorize its accreditation organization to release periodic status reports of correction progress since the accreditation organization would no longer monitor its correction progress.

g. We also proposed to delete the informal review procedures now specified in § 488.6(f) to assure that the appeals process is applied uniformly for all facilities participating in the program regardless of accreditation status.

h. We would also amend § 488.10, State survey agency review; Statutory provisions, to include the additional types of providers and suppliers in the statutory provision in paragraph (d) that concerns treating accredited entities as meeting conditions of participation or conditions for coverage.

i. We would update the cross-reference in § 488.11, which refers to validation surveys, from § 488.6 to § 488.7.

IV. Comments and Responses

We received comments from 66 commenters in response to the proposed rule we published on December 14, 1990. Commenters included professional organizations, individual providers and suppliers, accreditation organizations, State governments, consumer advocacy organizations, and consumers. While the commenters expressed overall support for the proposed regulation and approval of HCFA's "deeming" process, they also addressed a wide variety of issues. These issues included:

- Confidentiality and disclosure of survey information;
- Cost shifting through accreditation fees;
- Enforcement and quality of surveys;
- Duplication of surveys and fragmentation of responsibilities among accreditation, certification and licensure; and
- Inconsistency with OBRA '87 requirements.

General Comments

General Comments: We have summarized below those comments which do not pertain to a single specific section of the proposed regulations but, rather, related to the proposed rule in general.

Comment: Commenters expressed overall support for the proposed regulations and the process by which HCFA will grant deeming authority to national accreditation organizations.

Response: We acknowledge the broad support for the proposed regulation and have developed a final rule consistent with that support.

Comment: We received several comments with respect to JCAHO. One commenter expressed explicit support for JCAHO being recognized as an accreditation organization. A few commenters expressed concern about JCAHO's current performance as an accreditation organization. A summary of those comments are as follows:

- Statistics show that when JCAHO finds fault with its accredited facilities, the problems it cites are usually limited to issues of recordkeeping and documentation.
- Given the history of serious violations of many JCAHO accredited facilities, close scrutiny of JCAHO's requirements and survey process is necessary. The commenters also expressed concern about the absence of a toll-free hotline telephone number and the unaffordable fee of $100.00 that the JCAHO charges the public and consumer advocate organizations for information pertaining to the facilities it accredits.

Response: We will examine these issues when we conduct a review of any accreditation organization requesting deeming authority or through the annual deeming authority review of these organizations. We will publish a proposed notice in the **Federal Register** describing the basis for granting an accreditation organization deeming authority and provide opportunity for comment. We will subsequently publish a final notice in the **Federal Register**. We will also publish a notice whenever deeming authority is removed. We also note that section 1865(a) of the Act already gives explicit deeming authority to the JCAHO with respect to hospitals, except for utilization review requirements and any standards promulgated by the Secretary that are higher than JCAHO accreditation requirements.

Comment: Nine commenters stated that the deeming authority application process should be outlined in the regulations and believed that accreditation organizations that have been denied approval for deeming authority should be afforded the opportunity to resubmit their applications. Additionally, the commenters recommended that a decision on all applications for deeming authority should be made by HCFA no later than 60 days after an application is filed or refiled.

Response: We have accepted the comment concerning the application process and inserted the application process at § 488.4 of this rule. We feel that the inclusion of the application process and requirements is appropriate and, by specifying those items the accreditation organization must furnish, we set forth additional general criteria that will be used in evaluating applications for approval of deeming authority.

We do not, however, agree with the recommendation that we make a decision on all applications for deeming authority within 60 days. We must reserve the right to establish and alter such timeframes to assure the flexibility necessary to respond appropriately to applications that could affect large numbers of facilities.

- With respect to the application process, accreditation organizations wishing to apply to HCFA for "deeming authority" must provide the following information:

* The provider or supplier type(s) for which the organization is requesting "deeming authority";

* A detailed comparison of individual accreditation requirements with the equivalent Medicare conditions; i.e., crosswalk;

* A description of the accreditation organization's automated data system, including the kinds of reports and tables generated by that system;

* A detailed description of the survey process, including:

—the frequency of surveys;
—whether surveys are announced or unannounced;
—copies of survey forms and survey guidelines and/or instructions;
—the accreditation survey review process and decision-making process; and
—the steps taken to monitor the correction of deficiencies;

* Detailed information about who performs accreditation surveys, including:

—the size and composition of individual accreditation survey teams;
—the education and experience requirements those surveyors must meet; and
—the content and frequency of the in-service training provided to survey personnel;

* Policies and procedures regarding withholding or removal of accreditation status for facilities that fail to meet the accreditation organization's standards, or any other remedial actions taken by the organization with respect to noncompliance with its own standards;

* Current procedures employed to investigate complaints against accredited facilities;

* Duration of accreditation;

* A listing of all currently accredited facilities that would achieve deemed status upon approval of deeming authority and the expiration date of each facility's current accreditation; and

* Additional supporting documentation, including an agreement to notify HCFA of certain events, such as the removal of accreditation from a provider or supplier, and to conform accreditation requirements to changes in Medicare conditions.

• HCFA will notify an organization if it finds that additional information is required.

• The accreditation organization will receive a formal notice from the HCFA Administrator stating whether the request for "deeming authority" has been approved or denied and an explanation of the reasons for the denial.

• Approval of an accreditation organization will be for a six-year term. We have established a six-year term of approval because we believe it would be irresponsible and unreasonable simply to approve an organization for an indefinite amount of time and not provide for further comprehensive reviews. Since HCFA has discretionary authority with respect to the approval of accreditation organizations, we must be able to impose reasonable conditions, such as the six-year approval term, in order to ensure the health and safety of patients and the general public.

• All requests for "deeming authority" should be mailed to: Administrator, Health Care Financing Administration, room 700 East High Rise Building, 6325 Security Boulevard, Baltimore, Maryland 21207.

• A national accreditation organization whose request for deeming authority has been denied may request that its original application be reconsidered in accordance with the procedures in this rule or it may resubmit its application in its entirety as soon as the organization has made improvements in its accreditation program to meet Medicare requirements.

Comment: Eight commenters stated that it is not clear how the regulatory notice provisions would apply to individual accreditation organizations at the point of, or during, the process of application for deeming authority. Specifically, they requested clarification on:

• Whether public notice would be provided at the point an organization applies for deeming authority;

• Whether public notice would be provided that would identify the organizations that have not been granted deeming authority, including the basis for denial; and

• Whether there would be an opportunity for public comment on applications submitted by individual accreditation organizations.

Response: Because this rule could have broad applicability with respect to potentially large numbers of affected health care providers, facilities and consumers, we are enthusiastically committed to providing adequate notice and comment opportunities with respect to the approval of deeming authority for any accreditation organization. We believe that the proposed approval of deeming authority for an accreditation organization should be publicized and that the public should be offered the opportunity to comment on the proposed approval so that any final determination regarding such approval would be made only after consideration of all information and perspectives provided by interested and affected parties.

Therefore, we have revised the final rule to provide for publication in the **Federal Register** of a proposed notice with comment period whenever we determine that an accreditation organization has demonstrated that it can provide reasonable assurance that the entities it accredits meet the appropriate Medicare requirements and the rationale for the determination. At least six months after the publication of the proposed notice, we will publish a final notice before any approval of deeming authority becomes effective.

Comment: Four commenters believed that the proposed regulations should include State licensure agencies as organizations that can be approved for "deeming authority" if these agencies have both survey and enforcement programs that meet HCFA's standards. The commenters also believed that when the proposed regulations are implemented, the State should be given first "refusal rights" for recognition as the accreditation organization because State agency personnel have received training on the survey and certification processes and are knowledgeable about the Medicare certification requirements. One commenter also believed that in some situations a State or regional program may be better equipped to understand and accommodate State laws when ascertaining compliance.

Response: We cannot accept this comment because under the authority of section 1865(a) of the Act HCFA is permitted to grant deeming authority only to national accreditation organizations.

Comment: One commenter indicated that the term "national accreditation organization" needs to be clarified.

Response: A national organization is an accreditation organization that offers accreditation services that are available in every State to any provider or supplier of the type accredited by the organization wishing to obtain accreditation status.

Comment: Four commenters stated that granting authority to private accreditation organizations creates a significant potential for inhibiting redress of consumer grievances and fails to provide sufficient consumer and beneficiary representation.

Response: We do not agree with this comment. The deemed status validation process includes a complaint investigation process. As indicated in § 488.7(a)(2) of this rule, the State survey agency, in response to a substantial allegation of noncompliance, surveys for any condition, or requirement for SNFs, that HCFA determines is related to the allegation. We have defined the term substantial allegation of noncompliance to mean a complaint from a variety of sources (including complaints submitted in person, by telephone, through written correspondence, or in newspaper or magazine articles), or any other source, that reflects on the health and safety of patients and raises doubts as to a provider's or supplier's compliance with any Medicare condition level requirement.

Comment: One commenter urged that HCFA work with entities such as the American Hospital Association, the JCAHO, the College of American Pathologists, the American Society of Internal Medicine, and the Commission on Office Laboratory Assessment, all of which potentially will request "deeming authority" as national accreditation organizations; the commenter added that these entities have the knowledge and expertise to provide HCFA with valuable information in finalizing these regulations. Four commenters suggested that HCFA consult with professional organizations to investigate alternatives to the proposed 20 percent rate of disparity. The commenters suggested that one alternative would be to engage an independent body to undertake a nation-wide, on-site review of a sample of the facilities accredited by an organization and report its findings back to HCFA. The commenters believed that such an approach would reduce the impact of varying State standards and survey techniques and would allow these important decisions about

possible withdrawal of deeming authority to be based on a larger and more diverse national sample.

Response: The standard process by which we respond to comments on a published notice of proposed rulemaking offers an efficient and effective means to request and obtain input from the broadest possible spectrum of the public. In addition, there will be a proposed notice published in the **Federal Register**, and an opportunity for comment before the final approval of deeming authority for any accreditation organization. To include only a few organizations in drafting final regulations would, at best, be soliciting repetitive and subjective comments from these parties, and, at worst, allow for inequitable opportunity of certain parties to influence the agency's reaction to public comments and the ultimate formulation of policy. We will not allow an outside organization to develop criteria to measure the equivalency of standards nor to conduct a nationwide validation activity on our behalf because of the importance of ensuring sound, consistent, national policy on these issues.

Comment: One commenter stated that the proposed regulation does not refer to laboratories; there is no mention of how this regulation will be applied and its relationship to the Clinical Laboratory Improvement Amendments of 1988 (CLIA '88).

Response: We acknowledge the commenter's concerns that the proposed regulation did not discuss the deeming of accreditation of laboratories in significant detail nor does it explain the relationship between this rule and the implementation of the requirements of CLIA '88.

Regulations implementing CLIA '88 were published on February 28, 1992 (57 FR 7002) and January 19, 1993 (58 FR 5215): Medicare, Medicaid and CLIA Programs; Regulations Implementing the Clinical Laboratories Improvement Amendments of 1988 (CLIA '88). We also published, on July 31, 1992, a rule entitled, HSQ–81–F: Granting and Withdrawal of Deeming Authority to Private Nonprofit Accreditation Organizations and of CLIA Exemption Under State Laboratory Programs (57 FR 33992), to implement CLIA '88 requirements concerning deeming authority for accreditation organizations and States that accredit or license, respectively, laboratories. CLIA '88 has specific requirements for deeming laboratories as meeting CLIA requirements by virtue of their accreditation or licensure.

This final rule includes provisions only with respect to the granting and withdrawal of deeming authority to national accreditation organizations for the other provider and supplier types specified in the proposed rule, and only with regard to non-laboratory service requirements. Of the provider and supplier types for which national accreditation organizations may apply for approval of deeming authority, three have condition level requirements for laboratory services: hospitals; long-term care facilities; and ambulatory surgery centers. These condition level Medicare certification requirements require that a laboratory in an accredited facility meet the applicable requirements for a CLIA certificate and that the CLIA approved laboratory services be adequate to the needs of the patients in the facility. For example, once the CLIA certification requirements are effective, laboratories in accreditated hospitals will not have deemed status by virtue of their hospital accreditation by JCAHO or AOA. Therefore, a national accreditation organization may apply for deeming authority for all conditions for these provider types under this rule. However, if an organization wishes to have deeming authority for CLIA requirements, it must make separate application for that approval under the laboratory deeming rule. In all cases, a provider or supplier must provide CLIA certified laboratory services, either directly or under arrangement, in order to meet Medicare certification requirements.

Comment: Two commenters recommended that before issuing a final regulation, HCFA should commission an independent study comparing the private accreditation systems (including their ability to find violations that affect patients' health, safety or welfare, and to secure elimination of those violations) and the certification system mandated by the Omnibus Budget Reconciliation Act of 1987 (OBRA '87) (a system that is an outcome-oriented process that evaluates the standard of care furnished to residents based on outcomes of care, protection of resident rights, and then ensuring that the residents' well-being is not compromised).

Response: As provided for in § 488.9 of this rule, each accreditation organization applying to HCFA for deeming authority will be reviewed on a case-by-case basis. This process will evaluate accreditation systems more effectively than doing an overall comparative study. HCFA's evaluation of accreditation systems does not focus on the relative merits of one organization against another but on each organization's equivalency to the applicable Federal requirements.

Comment: Two commenters asked how the "deemed status" would work when a nursing home participates in both Medicare and Medicaid and questioned whether only the Medicare portion would be "deemed" if it had a Medicare distinct part.

Response: Because there is no statutory authority for granting deemed status to Medicaid nursing facilities, the deemed status granted by an accreditation organization would only apply to the Medicare certification of a dually participating facility or its dually participating distinct part(s). This may result in multiple surveys if any accreditation organizations request approval to grant deemed status to nursing homes and their accredited facilities participate in both Medicare and Medicaid. One survey would be conducted by the accreditation organization for the Medicare certification and another survey would be conducted by the State survey agency for Medicaid participation. The only instances where eligibility for Medicaid participation can be established through deemed status are for providers and suppliers that are only required under Medicaid regulations to comply with the Medicare participation requirements for that provider or supplier type. In such instances, if the accreditation body has received approval of deeming authority under Medicare, and if the provider or supplier is deemed to meet Medicare requirements by virtue of its accreditation by the approved accreditation body, that provider or supplier has met Medicaid requirements. Under present Medicaid rules, the only facilities subject to Medicare participation requirements are hospitals, home health agencies, laboratories and rural health clinics. We have revised §§ 488.5 and 488.6 to include deeming of Medicaid providers and suppliers where applicable.

OBRA '87 Comments

The Omnibus Budget Reconciliation Act of 1987 (Pub. L. 100–203) mandated nursing home reform and was comprised of numerous provisions addressing comprehensive requirements for resident health, safety and rights in order for nursing homes to participate in Medicare and Medicaid. OBRA '87 also specified an innovative survey and enforcement mechanism to ensure facility compliance with these requirements. We received several comments about how our proposed rule is affected by OBRA '87 changes.

Comment: Twelve commenters questioned the legality of "deemed

status" and its consistency with the intent of the nursing home reform provisions of OBRA '87. The commenters believed that accreditation organizations will not be able to demonstrate that their standards are equivalent to the equivalent standards of OBRA '87.

Response: Section 1865(a) of the Act specifies that if HCFA finds that the accreditation of certain listed entities by a national accreditation organization provides reasonable assurance that the Medicare conditions imposed on those entities are met, it may treat such an entity as meeting those conditions. Included in the list of entities in section 1865 of the Act are skilled nursing facilities. The ability of an accreditation organization to demonstrate that its standards are equivalent to corresponding standards of OBRA '87 cannot be ascertained until that organization applies for deeming authority and HCFA completes a comparative analysis. Only if the accrediting organization conclusively demonstrates that its standards are at least equivalent to the OBRA '87 requirements for skilled nursing facilities would we consider granting deeming authority for these types of facilities.

OBRA '87 made sweeping changes in nursing home requirements, survey and enforcement, with which an accrediting organization could have difficulty demonstrating equivalence. The law requires public accountability and access to public information that goes well beyond the deeming provisions of the statute and that requires State agencies to use their survey responsibilities in administering a complex system of quality assurance initiatives.

The likelihood that any national accreditation organization will request approval of deeming authority for long-term care facilities appears to be low because only 870 of the currently 16,297 certified long-term care facilities participate only in the Medicare program. The number of Medicare-only facilities has steadily decreased as more facilities elect to participate in both Medicare and Medicaid, and we anticipate this trend continuing. Facilities that participate in both programs may decide not to seek accreditation for purposes of deeming since the facility would then be subject to two surveys; that is, an accreditation survey for deeming of the Medicare requirements and a survey by the State agency for Medicaid participation. The increasingly limited number of facilities that could benefit from accreditation for deeming purposes would make an unattractive market for accreditation organizations as the survey system necessary to support a deeming authority program would prove costly to the organization.

Comment: Six commenters expressed concern that accreditation organizations would not be required to use interpretive guidelines consistently that were developed for surveyors to survey nursing homes and home health agencies.

Response: Although the use of HCFA's interpretive guidelines would not be required, the accreditation organization must demonstrate that it can provide reasonable assurance that the requirements of the nursing home reform provisions of OBRA '87 are met. We expect an accreditation organization applying for deeming authority to have survey guidelines and procedures that will assure consistent application of their standards and provide reasonable assurance to HCFA that the participation requirements would be met if the facility were surveyed for compliance with those requirements.

Comment: One commenter suggested that delegating oversight authority to an accreditation body is not sound policy, especially in light of changes mandated by OBRA '87, which radically revised how we determine whether a nursing home may participate in Medicare and Medicaid.

Response: Congress has granted deeming status to JCAHO since the inception of the Medicare program. Congress further authorized the Secretary at section 1865 of the Act to permit other types of providers and suppliers to be deemed by accreditation bodies if those accreditation bodies provide reasonable assurance that the applicable participation requirements are met. By granting deeming authority the Secretary does not delegate oversight authority. The oversight authorization with respect to participating facilities remains with HCFA, who may take enforcement actions on the basis of surveys performed by the accreditation organization, the State survey agency, or both. The approval of deeming authority for OBRA '87 nursing home provisions will only occur if an accreditation body applies for such deeming authority and provides reasonable assurance that its accredited facilities meet the OBRA '87 nursing home requirements.

Comment: Two commenters believe that important issues such as improper and overuse of chemical and physical restraints, pharmacy care and resident rights could easily be overlooked by private accreditation organizations.

Response: As we have stated earlier, when an accreditation organization requests approval to grant deemed status, that organization must provide reasonable assurance that Federal requirements for each type of provider to which it wishes to grant deemed status will be met and that it can consistently survey accurately for those requirements. If these assurances are not provided, we will not approve the organization.

Comment: One commenter said there appeared to be a direct conflict with OBRA '87 provisions, which require the imposition of incremental fines for repeated or uncorrected deficiencies, and the concept of reasonable assurance and findings of significant deficiencies that appear to provide for an acceptable level of noncompliance.

Response: There is no acceptable level of noncompliance with Federal requirements. Only through a careful comparative analysis can we determine whether an accreditation organization provides reasonable assurance that all Federal requirements are met by accredited facilities. We will not grant approval of deeming authority to any organization whose standards or survey process permit noncompliance with the applicable Federal requirements. The use of the sanction provisions of OBRA '87, that is, denial of payment for new admissions, civil money penalties, temporary management, etc., can be used in addition to any actions an accreditation organization takes when it finds noncompliance, because the Omnibus Budget Reconciliation Act of 1989 (OBRA '89) specifies that we can take action based on an accreditation organization's findings. Accordingly, we may impose incrementally more severe fines for repeated or uncorrected deficiencies cited by the accreditation organization in its survey documentation. We may also impose sanctions based on our own survey when HCFA removes a provider's deemed status. For cases in which HCFA takes an adverse action based on an accreditation organization's findings, we have included a requirement in § 488.4 that in its application for deeming approval an accreditation organization must agree to permit its surveyors to serve as witnesses.

Comment: One commenter stated that since no final rules have been issued to implement any OBRA '87 provision, there exists no basis for consideration of granting deemed status to nursing facilities and home health agencies at this time.

Response: The process involved in approving accreditation organizations for deeming purposes does not require

that the provisions of OBRA '87 be implemented. We will grant deeming approval to accreditation organizations whose accreditation requirements are equal to or more stringent than the requirements we have in effect at the time. However, we do note that the OBRA '87 provisions have been included in several regulations: "BPD–396–FC: Requirements for Long Term Care Facilities", published February 2, 1989 (54 FR 5316), "BPD–396–F: Requirements for Long Term Care Facilities", published on September 26, 1991 (56 FR 48826), and "BPD–76–F: Home Health Agencies; Conditions of Participation", published on July 18, 1991 (56 FR 32973).

Comment: One commenter believed that approving an accreditation organization that uses a medical model rather than patient outcomes is contrary to nursing home reform provisions of OBRA '87, which stress quality of life for residents and pays closer attention to social and emotional needs.

Response: Although historically accreditation organizations have focused on compliance with process standards, any accreditation organization seeking approval to grant deemed status must demonstrate that it has requirements equivalent to all of the HCFA requirements for the same facility type, including those addressing social and emotional needs and patient outcomes in general. We also expect an organization to demonstrate a survey procedure and overall philosophy compatible with the OBRA '87 requirements, which mandated a survey process that evaluates resident outcomes, rather than focusing on policies and procedures, and provides for enforcement sanctions other than termination if facilities are out of compliance. These issues will be examined when an organization applies for approval to grant deemed status to any type of provider or supplier.

Comment: Four commenters expressed concern that the Joint Commission routinely announces its surveys three months in advance, which gives facilities ample time to prepare for the accreditation survey, while OBRA '87 requires that surveys be unannounced so that facilities will not be able to cover up the failings and inadequacies of the facility cosmetically.

Response: Any accreditation organization requesting approval to grant deemed status must assure and demonstrate to the Secretary that its surveys conform to Federal survey requirements. In fact, our policy is also to announce hospital surveys. We will examine the survey process of any accreditation organization wishing to grant deemed status to nursing homes to determine if it includes a survey policy consistent with the requirements of the law and HCFA operating policy.

Comment: Fifteen commenters believed there will be duplication, overlap and fragmentation of responsibilities if the Secretary allows accreditation organizations to grant deemed status to nursing homes and home health agencies (HHAs). They argued that nursing homes and HHAs would have to be licensed by the State and, additionally, by the accreditation organization. They stated that these surveys would be conducted at different intervals.

Response: In nursing homes and HHAs, State licensure and HCFA surveys are separate but in most cases are conducted concurrently. OBRA '87 requires that surveys be unannounced and allows the State survey agency to conduct a survey up to 15 months from the last survey as long as the Statewide average does not exceed 12 months. Any accreditation organization requesting approval would likely demonstrate a similar mechanism to assure an unannounced aspect and an acceptable frequency of surveys, and we are revising § 488.8(1)(ii)(B) (proposed § 488.9(1)(ii)(B)) to cite specifically whether surveys are announced or unannounced as one of the survey procedures we will include in determining comparability.

Comment: Three commenters asked that accreditation organizations be held to the same timeframes for conducting surveys and releasing the survey findings to providers as the State survey agency. One commenter further asked that the length of accreditation should be flexible based on the facility's ability to meet standards; another expressed concern that accreditation status was generally conferred for a three-year period.

Response: Accreditation organizations will have to demonstrate to HCFA that they use survey processes, survey frequencies and other timeframes that provide reasonable assurance that Medicare requirements, whether designated in law, regulations, or manual instructions, are met for the types of facilities for which the accreditation organization is seeking approval to grant deemed status. The statute does permit survey intervals of as much as 15 months for nursing homes and HHAs, and there is nothing to preclude such intervals from being set by an accreditation organization based on the facility's past performance. The specific timeframes and other procedures used by an accreditation organization will be evaluated by HCFA during the application process, as will the mechanisms used by the organization to monitor facilities and ensure compliance with requirements during the periods between surveys.

Comment: Twenty-one commenters questioned the advisability of dividing the survey and enforcement functions when an accreditation organization is approved to grant deemed status. Commenters stated that—

- The quality of the survey will be compromised by possible differences in interpretation of Federal regulations.
- Survey and enforcement processes are inextricably linked. Results of the surveys dictate the enforcement remedies, and enforcement needs must guide the survey (i.e., assuring that the survey documentation will withstand legal challenges).
- When the survey is performed by an outside entity, there will be no information released on substandard facilities and no enforcement actions taken while residents live in poor quality and sometimes life-threatening circumstances.
- Granting approval to an accreditation organization undermines the government's ability to perform quality assurance and protection of nursing home residents from abuse and neglect.

Response: All accreditation organizations must provide reasonable assurance that applicable standards will be met, as ascertained by HCFA through our comparative analysis, before an organization will be approved for granting deemed status. Accreditation organizations will be applying their own standards and will not be interpreting Federal regulations. Further, we are authorized to accept the accreditation organization's survey as our own in imposing sanctions, so the survey and enforcement processes remain closely associated. The government expects accreditation organizations to enforce requirements for quality assurance and for assuring resident protection. The validation activity will further demonstrate whether the organization's application of its standards meets HCFA enforcement needs and provides reasonable assurance of compliance. Additionally, the validation authority for State survey agencies to survey accredited facilities encompasses both routine validation reviews and other reviews stemming from complaints and can help to ensure the health and safety of patients and residents. Finally, we can require accreditation survey information to be available for substandard facilities to the extent the

information results in an enforcement action.

Comment: Nine commenters stated that the proposed rule does not take into account the interrelationships of the survey to other critical quality assurance functions and that no accreditation organization could be responsive in a consistent and timely manner to investigations of abuse since the accreditation organization would not share its findings and has no jurisdiction or authority to act on behalf of someone found to need assistance. The commenters added that, although the proposed rule requires an accreditation organization to have the ability to investigate complaints, there is no requirement for the investigations to be coordinated with other responsible agencies.

Response: The relationship between an accreditation organization, the State ombudsman for long term care and the State will be evaluated to assure that the accreditation organization meets the coordination requirements of OBRA '87. We will consider such relationships in determining whether the organization that seeks deeming authority for skilled nursing facilities has a survey process that provides reasonable assurance that the standards dictated by OBRA '87 and codified in section 1819(g) of the Act will be met and should therefore be approved for deeming authority. Specifically, an accreditation organization seeking approval for skilled nursing facilities will be expected to have procedures in place to notify the State ombudsman when it identifies deficiencies in an accredited facility with respect to its accreditation standards as well as any adverse action taken with respect to the facility's accreditation status. The accreditation organization will also be expected to notify each attending physician and the State board that licenses nursing home administrators whenever the accreditation organization identifies one or more instances of substandard care in an accredited facility.

Comment: Two commenters believed that granting deeming authority to an accreditation organization increases the time between the discovery of a deficiency and the application of a remedy because the survey agency would need to conduct another survey before imposing remedies.

Response: While the State agency is not precluded from conducting another survey, Section 1865(b) of the Act as amended by section 6019(b) of OBRA '89 permits HCFA to accept the accreditation organization's findings as its own and impose remedies immediately. To further ensure the protection of the health and safety of patients and residents in accredited facilities, we will require in § 488.4(b)(3)(vi) an approved accreditation organization to agree to notify HCFA within ten days whenever it identifies a deficiency that poses an immediate jeopardy to those patients or residents.

Comment: Two commenters recommended that validation/complaint surveys be conducted by a disinterested party, such as the Office of the Inspector General, and not by HCFA agents, to yield more objective and fair results.

Response: As stipulated in Section 1864(c) of the Social Security Act, there is no statutory authority for the Secretary to delegate this function to any entity other than the State survey agency.

Comment: One commenter believed that if more than one national accreditation organization exists, competition for contracts with nursing homes could undermine the survey process by creating a potential conflict of interest between the facility and an organization that accredits it.

Response: Accreditation is strictly voluntary. While it is possible that a facility could "shop around" for an accreditation organization whose standards the facility could meet, if the accrediting organization has approval of deeming authority its standards as a whole will have been found to provide reasonable assurance that equivalent Federal requirements would be met.

Cost Issues

Comment: One commenter believed that diverting survey dollars to an accreditation organization would weaken the capacity of the designated government survey agency to respond to substandard conditions.

Response: Accreditation fees for hospitals have always been an allowable cost under the Medicare program and included in a facility's indirect costs or in its prospective payment rate for inpatient services. The allowable costs considered reasonable are allocable on the basis of Medicare patient days or are reflected in a hospital's prospective payment rate for inpatient services. This rule will not divert survey dollars or reduce the enforcement funding of survey agencies. The level of funding of the State's survey agency will continue to be based on its survey and enforcement workload. Funding of State survey agencies will be commensurate with workload and number of facilities involved and will take into account the responsibility to "respond to substandard conditions".

Comment: One commenter believed that extending an accreditation program to nursing homes is not appropriate because it increases the administrative costs of regulating nursing homes. He believed these funds should go for direct care services for residents.

Response: As explained above, extending an accreditation program to nursing homes will not increase administrative costs since the Federal government will either pay the accreditation fees allocable to the Medicare program or pay the cost of a State agency survey of the facility.

Comment: Twenty commenters believed that "deemed status" shifts costs to the public from one budget to another. They stated that fees to accreditation organizations are paid by providers, which are in turn reimbursed for their expenses as part of their allowable operating costs of doing business. The commenters were concerned that this fee-for-service arrangement reduces public accountability and objectivity and that, consequently, the Federal government will still be paying for the accreditation surveys.

Response: While it is true that accreditation fees are considered an allowable cost, those costs are allocable on the basis of the Medicare population in a facility or are reflected in the calculation of a hospital's prospective payment rate for inpatient services. Since the remaining accreditation costs will be borne by the facility, there is not a dollar-for-dollar shifting of survey costs. We will evaluate factors such as cost, public accountability, conflict of interest, and objectivity through the review of an accreditation organization's application for approval of deeming authority.

Specific comments: The following are comments we received on specific regulatory sections:

§ 401.126 Information or records that are not available.

§ 401.133 Availability of official reports on providers and suppliers of services, State agencies, intermediaries, and carriers under Medicare.

Comment: Twenty-seven commenters believed that, based on the OBRA '87 provisions related to public accountability and access to public information, all survey results, including accreditation surveys, should be made available to allow consumers to make comparative judgements about certified providers and suppliers. Moreover, the commenters believed that the accreditation survey confidentiality requirements are inconsistent with OBRA '87 provisions on disclosure and

will abridge the effectiveness of ombudsmen as a source of information about a facility.

Response: Section 1865(a) of the Act prohibits disclosure of accreditation surveys or related information by the Secretary except to the extent that these surveys and information relate to an enforcement action taken by the Secretary. Copies of all accreditation survey information will be available to HCFA, which will monitor accreditation organizations and the facilities they accredit. We will take enforcement action if deficiencies are not corrected by the facility; the accreditation survey and related information with respect to the enforcement action will be available to the public. In this way, there is access by the public to information about poor performance on the part of accredited entities. Although this provision at Section 1865(a) of the Act does not speak to the release of information on good performance by nursing homes, the primary objective of the nursing home provisions of OBRA '87 was the protection of the health and safety of residents. Disclosure of information on poor performers that the public would want to avoid is certainly consistent with that objective of OBRA '87. While Section 1819(g)(5)(A)(i), as added by OBRA '87, requires us to make available to the public survey and certification information about all SNFs (not only those that are subject to enforcement actions), Section 1819 of the Act mentions only surveys conducted by the State or the Federal government and is silent on those conducted by accreditation organizations. However, when we evaluate an accreditation organization's application for deeming authority, we will consider all of the issues raised in the above comment. In addition, while Section 1865(a) of the Act prohibits us from disclosing accreditation survey information, unless an enforcement action is taken on the basis of that survey, or any accreditation survey of a home health agency, there is nothing in the statute to preclude the accrediting organization from releasing this information. In addition, we do not prohibit the release of this information by the individual facilities. The responsiveness of an accreditation organization to public inquiries about surveys of individual facilities, or a facility's willingness to release survey information, are factors consumers can consider in evaluating the facility. Based on these factors, the consumers can reach their own conclusion about a facility's performance and management philosophy, and the relative value to consumers that accreditation by a certain organization may have. As mentioned previously, we will evaluate an accreditation organization's level of coordination and cooperation with State ombudsmen programs when we receive the organization's application for deeming authority.

Finally, where ombudsmen function as an agency or otherwise are under the aegis of the State government, Federal law does not preclude the enforcement of State laws requiring the disclosure of accreditation information, for example, under State licensure programs.

Comment: One commenter requested clarification on the kinds of actions HCFA will consider as "enforcement actions" under § 401.126(b)(2)(B) of this rule.

Response: An enforcement action may include any action the Secretary takes in response to noncompliance with Federal requirements. Such sanctions include termination and other remedies that are alternatives to termination. We have amended the text at §§ 401.126(b)(2)(B) and 401.133(d) to include some examples of enforcement actions.

Comment: Two commenters recommended that § 401.133(d) be revised to require (rather than allow) the Secretary to release the accreditation survey and related information upon request. The commenters believed that this change is needed to achieve equivalency to the current Federal survey policy.

Response: We accept this recommendation and have amended the text at § 410.133 (d) and (e) to state that HCFA will release the information, rather than that we may release it. We are also changing, in other sections, all references to "the Secretary" to "HCFA" to correspond to other HCFA regulations. For consistency with the release of accreditation surveys of entities other than HHAs, in paragraph (e) we will require the release of HHA surveys only upon written request.

Comment: Two commenters objected to the proposed provisions in §§ 401.126 and 401.133, which state that the Secretary may release the accreditation survey of any home health agency. One commenter believed that in accordance with Section 1864(a) of the Act, the Secretary is authorized, at most, to release only certain accreditation survey information concerning significant deficiencies with respect to patient care to the State survey agencies so that they may make that information available over the home health hotline. The commenters believed that the disclosure of home health agency accreditation survey information should be similar to disclosure for other providers or suppliers.

Response: Section 1865(a) explicitly prohibits the Secretary from disclosing the accreditation survey released to HCFA by any accreditation organization for any entity other than a survey with respect to a home health agency (except that the Secretary may disclose survey results and information related to the survey for any type of facility to the extent that the survey and additional information are related to an enforcement action the Secretary takes). Accordingly, the law does not prohibit the Secretary's disclosure of accreditation surveys of home health agencies. Therefore, based on the law, we do not accept these comments.

Section 488.1—Definitions

Comment: Four commenters recommended that the definition of a substantial allegation be revised to define the sources of complaints more specifically. The commenters believed that the revision will reduce instances of rumor and speculation.

Response: We do not agree that specifying or explaining the sources of complaints in regulations will reduce unsubstantiated allegations. Our administrative procedures manuals provide guidance to Federal and State surveyors to evaluate all complaints. Those complaints that pertain to charges and billing, health insurance coverage, and personal complaints that are clearly subjective are not authorized for investigation. We believe, however, that all complaints, regardless of the source, concerning the quality of care and other participation requirements must be investigated. Specific investigative procedures are included in the procedure manuals. However, writing regulations to this level of specificity would unnecessarily limit HCFA's flexibility in applying its administrative policies.

Comment: One commenter asked that we define the term "reasonable assurance" as specified in section 1865 of the Act and as it relates to the accreditation process in § 488.1.

Response: We have accepted this comment and are defining "reasonable assurance" in § 488.1 to mean that an accreditation organization has demonstrated to HCFA that its standards, taken as a whole, are at least as stringent as those established by HCFA, taken as a whole. This does not mean that the requirements of the accreditation organization must be identical to HCFA requirements. The accreditation requirements may vary from and be organized differently than the Federal requirements for a specific

service or facility. It is possible that an accreditation organization may impose less stringent requirements in one area that are balanced by more stringent requirements in a closely related requirement elsewhere in the standards. The main consideration in determining reasonable assurance is the level of protection afforded to the accredited facility on the basis of the accreditation requirements taken as a whole. We have revised the proposed § 488.6 to reflect this policy.

Comment: One commenter stated that a definition for "pattern of increasing disparity" should be developed.

Response: We have deleted references to increasing rate of disparity and have revised our approach in using the rate of disparity in determining whether a comprehensive review of an accreditation organization's deeming authority should be undertaken. As provided in the final rule, at the close of a validation review period, we will evaluate the findings of the validation program, including the rate of disparity. If the rate of disparity is 20 percent or more, we will initiate a deeming authority review. On the basis of validation review findings where the rate of disparity is less than 20 percent, we may implement deeming authority review if the validation review findings indicate widespread or systematic problems in an organization's accreditation process that provide evidence that there is no longer reasonable assurance that accredited entities meet Medicare requirements.

Section 488.5—Effect of JCAHO or AOA Accreditation of Hospitals

Comment: Two commenters stated that under § 488.5(b) all accreditation findings for any hospital should be automatically released to HCFA.

Response: Section 1865(a) of the Social Security Act provides that only if an accredited hospital authorizes the accreditation organization to release its most recent accreditation survey will a hospital be deemed to meet the Medicare requirements. The regulation at § 488.5(b) simply restates this statutory provision. We will determine administratively when and under what circumstances (e.g., validation survey, complaint investigation, enforcement action, etc.) we will exercise our rights to secure this information as we do not necessarily have a need for records of all accreditation surveys.

Comment: One commenter believed that a provision needs to be included in § 488.5 that requires providers and suppliers to report substandard surveyors and erroneous accreditation survey reports to HCFA.

Response: Surveyor performance and accuracy of accreditation survey reports are issues that will be evaluated as part of the validation review process. When reviewing the performance and accuracy as part of the comparability review process, we will ensure that an accreditation organization has a quality control process, and evaluate the effectiveness of that process.

In determining whether the accreditation organization provides reasonable assurance that Medicare requirements are met, HCFA will review how the organization assures its surveyors are competent and that survey results are accurate. For this reason, we have declined to accept this comment. In addition, affected providers will have the opportunity to comment prospectively on the survey process and personnel qualifications at the time the proposed notice of approval is published. Finally, there is nothing to preclude any provider from notifying HCFA or the accreditation organization whenever the provider encounters problems in the accreditation process or survey personnel.

Section 488.6—Other National Accreditation Programs for Hospitals and Other Providers and Suppliers

Comment: Seven commenters disagreed with the proposed provision in § 488.6 that permits partial accreditation for providers that meet "any or all of the Medicare conditions". The commenters believed that such services as dietary, nursing, assessment, and quality of care are all interrelated. They stated that under an outcome-oriented system, a surveyor must look at the whole picture before determining compliance; partial accreditation would segment the information available to the public and segment enforcement efforts.

Response: The term partial accreditation is misleading. We have no authority over the services, facilities, or requirements that an accreditation organization chooses to evaluate and accredit. Based on an organization's scope of interest, we could be faced with the issue of partial deeming. We agree with the commenters that this concept could be problematic. As the commenters point out, many of the participation requirements are inextricably related and cannot be properly evaluated without careful examination of the related requirements. We also believe, however, that there could be effective accreditation organizations whose standards address individual participation requirements or groups of requirements that are less than the full range of requirements that a specific facility type must meet in order to participate in the Medicare program.

The statute gives the Secretary explicit authority to deem compliance with "any or all" of the Medicare conditions if equivalent accreditation standards are met. While we can see no advantage to recognizing partial accreditation at this time, the authority to do so is reflected in this rule. Deeming compliance with only a portion of the Medicare certification requirements could create an extreme administrative burden, but it can also provide the necessary flexibility to administer the certification program effectively. In addition to those cases where the accreditation organization accredits less than the full range of Federal requirements, there are those instances where we have imposed specific requirements that are more stringent than comparable requirements imposed by an accreditation organization. In such cases, deeming authority for the majority of the requirements could be an effective device that allows us or our agent to survey directly for some requirements and to allow for the deeming of others by a specific entity.

For example, currently accredited psychiatric hospitals are deemed to meet all of the hospital conditions for participation except the special psychiatric hospital staffing and records requirements, which HCFA surveys through other means. Other similar arrangements could prove desirable, and we must maintain the authority to exercise flexibility in the scope of deeming authority that is approved.

Comment: Two commenters strongly recommended that the proposed deletion of the informal review process currently specified in § 488.6(f) be retained and extended to all providers whether or not they are accredited.

Response: We do not accept this comment. As indicated in the preamble of the proposed regulation, we will implement a uniform appeals process for both accredited and nonaccredited providers and suppliers. Eliminating the informal review process for accredited providers and suppliers, which is not available to nonaccredited providers and suppliers, is part of our effort to establish this uniform appeals process.

Comment: One commenter believed that the proposed language in § 488.6 deviates substantially from the intent of the language specified in section 1865 of the Act. The commenter recommended that the language in § 488.6 be changed to specify that conditions precedent to accreditation recognition by HCFA include the requirement that the accreditation organization demonstrate

that it imposes the Medicare condition(s) or other requirements that serve substantially the same purpose or standards that HCFA determines are at least equivalent to the Medicare standards imposed by HCFA.

Response: Section 488.9 satisfies the intent of the law by outlining the general criteria an accreditation organization must meet in order to provide reasonable assurance to HCFA that its standards are equivalent to those standards established by HCFA. Therefore, we are not revising § 488.6 as suggested.

§ 488.7—Validation Survey

Comment: Two commenters supported the use of private accreditation survey results as the basis for triggering a validation survey but strongly objected to the initiation of enforcement actions based on an accreditation survey without independent verification of noncompliance through a Medicare survey.

Response: Under section 6019(b) of OBRA '89 HCFA may use a validation survey, an accreditation survey, or other information related to the survey to determine that a facility does not meet the Medicare conditions of participation. HCFA may, based on the results of an accreditation survey, remove "deemed" status and initiate an enforcement action against a facility based simply on a review of the accreditation organization's documents. Such immediate action is necessary to protect the health and safety of patients and residents in accredited facilities.

Comment: One commenter believed that significant deviations currently exist among regional offices and between regional offices and HCFA central office concerning the interpretations of the conditions of participation and that HCFA has not given instructions to its own surveyors on when to cite standard versus condition level deficiencies. He stated that surveyors' classifications of deficiencies vary and will likely continue to do so until HCFA develops more specific instructions on weighing systems for establishing consistency.

Response: The HCFA survey and certification procedures applied by the State survey agencies and Federal surveyors are not the subject of this rule. However, we point out that the survey and certification process includes review mechanisms to ensure that surveyors, in exercising their best professional judgement in identifying and citing deficiencies, are consistent in their application of the requirements. Based on our experience in evaluating State agency performance, we disagree with the comment that HCFA and the State agency survey are inconsistent with respect to citing deficiencies.

Comment: One commenter believed that providers certified on the basis of "deemed status" should be allowed to request a review by the State agency or the HCFA surveyors where accreditation findings indicate deemed noncompliance with Federal conditions; in such cases, the State or regional office surveyors could confirm the accreditation organization's findings or conclude that Federal requirements are met whether or not all standards of the accreditation organization are met.

Response: The law provides no authority for providers or suppliers certified on the basis of "deemed status" to choose to have a State survey when accreditation findings indicate noncompliance with accreditation standards and, therefore, presumed noncompliance with Federal requirements. Only HCFA has the authority to determine which accreditation survey results will be validated. A State agency survey will be available to a facility if the facility voluntarily discontinues its accreditation status or loses its accreditation due to noncompliance with accreditation requirements and formally requests certification by the survey agency. Otherwise, State agency surveys of accredited facilities will be done on a sample basis or in response to complaints, as explained below. Except in the situations noted above, neither HCFA nor the State agency will intervene in any dispute between an accreditation organization and its accredited providers or facilities.

Comment: Two commenters questioned whether the terms "significant deficiencies" and "reasonable assurances that conditions were met to the extent appropriate" allow an acceptable amount of facility noncompliance with HCFA requirements.

Response: We do not agree with this comment. As we indicated in the preamble of the proposed regulations, it is in the public's interest to follow up any deficiency serious enough to threaten a provider or supplier's participation in the Medicare program and we are revising the proposed regulations at § 488.7(a) to permit us to survey in response to substantial allegations of any deficiencies (instead of significant deficiencies). We have no authority to change the statutory provision that requires "reasonable assurances that conditions were met to the extent appropriate". However, we believe the criteria for determining reasonable assurance, as presented in this final rule, will assure that accredited facilities meet Medicare requirements. Our evaluation of an accreditation organization will determine the equivalency of the accreditation organization's facility standards, taken as a whole, and its survey and inspection requirements to the applicable Federal requirements. Equivalency means that the organization's requirements correspond to and provide at least the same protection as the applicable Medicare condition level requirements established by HCFA. It is acceptable for an accreditation organization's requirements to vary from and be organized differently from the HCFA requirements, as long as all of the accreditation organization's requirements, taken as a whole, are at least equal to the HCFA requirements, taken as a whole.

Comment: One commenter believed that § 488.7(b)(1), which requires the provider or supplier to authorize the release of its survey to HCFA, should be deleted because it is redundant of §§ 488.5(b) and 488.6(b).

Response: We agree with the commenter that the provision at § 488.7(b)(1) is essentially duplicative of the provisions at §§ 488.5(b) and 488.6(b) and have deleted that provision. To conform to the requirements of the statute, we have revised §§ 488.5(b) and 488.6(b) to reflect that a hospital or other facility deemed to meet Medicare requirements by virtue of accreditation must authorize the release of its accreditation survey to the State survey agency as well as to HCFA.

Comment: One commenter stated that § 488.7(a)(1) of the proposed regulation should be amended to allow the validation survey to focus on specific conditions when appropriate. This validation survey approach was permitted in a HCFA letter to the Joint Commission.

Response: We agree with the commenter and have revised the regulation at § 488.7(a)(1) to reflect that the validation survey may be focused on specific conditions or requirements when appropriate.

Comment: One commenter stated that the proposed regulation does not require validation surveys to be conducted with sufficient frequency, according to accepted scientific standards. Another commenter stated that under § 488.7(a), HCFA should conduct validation surveys within 60 days of the latest accreditation organization report to ensure the accuracy of the survey.

Response: Historically, the establishment of time limits for performing validation surveys of hospitals has been included within HCFA's internal operating instructions. Such time limits and procedures are subject to adjustment in response to changes in workload, staff resources, etc., as well as statistical reliability. The maximum allowable timeframe provided in our instruction manual for the interval between an accreditation survey and a corresponding validation survey is 60 days. However, based on recently revised procedures, we will also include in the representative sample of facilities for validation surveys facilities that have not had a recent accreditation survey (i.e., those that are at the midpoint of their accreditation cycle). When a validation survey is scheduled in a facility that has not had a recent accreditation survey, the State agency will be directed to perform the survey within 60 days of the survey request. We anticipate maintaining this threshold for accredited providers and suppliers subject to a validation survey.

Comment: One commenter recommended that HCFA clarify in § 488.7(e)(3), which concerns once again permitting deeming of a provider or supplier if we find it meets all the Medicare conditions, what effect condition level deficiencies will have on reimbursement. The commenter stated that current HCFA policy allows laboratories not in compliance with Medicare's conditions of participation to be reimbursed for a period of time when plans of correction are being implemented. He added that, accordingly, HCFA's administrative and operating procedures concerning termination and reinstatement should be included in the preamble.

Response: Reimbursement and laboratory issues do not come under the purview of this rule. Provider and supplier termination and reinstatement procedures are addressed in part 498, which addresses appeals procedures. The removal of a provider's or supplier's deemed status by HCFA for condition-level deficiencies is the customary first step in the termination process. HCFA procedures provide for a 23 or 90 day timeframe for termination depending on the scope and severity of the cited deficiencies. Providers and suppliers who are able to address the deficiencies to HCFA's satisfaction before the effective date of the proposed termination are not terminated.

Comment: One commenter believed that in § 488.7(a) (which lists the criteria under which we will review a national accreditation organization) the makeup of the team that will conduct any validation surveys should be specified; section 1819 of the Act, for example, recognizes the importance of specifying the makeup of the survey team.

Response: We do not accept this comment because we want to maintain the flexibility to ensure that the specific composition of validation survey teams is appropriate to the type of facility and to the circumstances of survey. For example, a complaint survey may be partial, focusing on certain requirements and may not require a full team.

Comment: Six commenters stated that the Joint Commission accreditation problems identified in testimony before the Subcommittee on Health of the House Committee on Ways and Means held in June 1990 have not been adequately addressed in the proposed regulation. One of the commenters believed that, based on this testimony, § 488.7(a) should be amended to include the following: (a) A minimum of five percent of all accredited providers of each provider type for each approved accreditation organization will receive a validation survey; (b) the rule should specify that a full survey shall be conducted for every instance in which the State agency substantiates a complaint regarding inappropriate treatment or inadequate quality of care; and (c) the terms "substantial allegations of significant deficiencies" should be changed to read, "a substantial allegation validated by the State survey agency." The commenter thought that more than one allegation is not necessary and the term "significant deficiencies" is very subjective and is not defined.

Response: In determining whether an accreditation organization provides reasonable assurance of compliance with Medicare requirements, all aspects of its survey and accreditation process will be subjected to examination. Concerning the size of the validation sample, we note that the statute does not require a particular sample size for validation surveys, and we do not believe it is necessary to establish such a sample size through regulation. Further, § 488.7(a)(2) specifically states that "If the State survey agency substantiates a deficiency * * * the State conducts a full Medicare survey." Accordingly, any substantiated instances of inappropriate treatment and inadequate care would trigger a full Medicare survey. As we have indicated earlier we are deleting references to significant deficiencies because we believe it is in the public's interest to follow up any alleged deficiency with respect to Medicare requirements. We have amended § 488.7(a) of the rule to reflect this policy.

Comment: Three commenters recommended that § 488.7(d) be revised to reflect that accredited facilities found out of compliance with Medicare requirements should be subject to the requirements for enforcement remedies applied to non-accredited facilities. The commenters believed that this section needs clarification to indicate that if found out of compliance during the validation survey the facility will be subject to the same enforcement remedies that may be imposed on a non-accredited facility.

Response: We have accepted this recommendation and have incorporated clarifying language in the text at § 488.7(d) of this rule.

Comment: Four commenters indicated their belief that the triggers for a validation survey as proposed by HCFA are seriously lacking. OBRA '87 requires that facilities meet "all" requirements, not just "substantial" and "significant" ones.

Response: We believe our triggers for a validation survey are consistent with the intent of OBRA '87; we will respond to every possible deficiency of any requirement that reflects on the health and safety of patients or residents or raises doubts as to a provider's or supplier's compliance with those requirements. As indicated earlier, we have deleted references to the term "significant deficiencies" and amended § 488.1 to reflect this policy.

Comment: Three commenters stated that the proposed regulation requires that a facility found through a validation survey to be out of compliance must be subject to termination. They believed that this proposal, by naming termination alone as a response to noncompliance, ignores the range of sanctions available under State law and under OBRA '87, which include denial of payment for new admissions, temporary management, and civil money penalties.

Response: We have revised § 488.7(d) to state that a facility may be subject to intermediate sanctions, if applicable to that type of provider, as well as termination. We have not included sanctions available under State law because Medicare participation does not fall under the State's jurisdiction.

Comment: One commenter believed there will be an increased burden on HCFA and State agencies due to performing validation surveys of deeming authorities.

Response: Under this rule, the State survey agencies, acting as HCFA's agents, will conduct validation surveys of accredited facilities. Since the States

are currently conducting all surveys, conducting only validation surveys for a sample of accredited facilities could represent a significant decrease in workload.

Section 488.9—Federal Review of Accreditation Organizations

A few commenters expressed opposition to the implementation of the provision at § 488.9(c)(2), which establishes the criteria and procedures for removing deeming authority based on validation reviews. A summary of the concerns expressed follows:

- One commenter indicated that the calculation for determining the rate of disparity assumes that HCFA will be able to develop a "crosswalk" to identify correspondences between Federal and private standards and that the private standards will be organized in the same manner as the Federal so that they can be aggregated to the "condition level".
- Two commenters recommended that the concept of a disparity rate be eliminated or held in abeyance until sufficient experience has been gained in inspecting laboratories under CLIA conditions.
- One commenter believed that tolerating a rate of disparity of up to 20 percent between findings of the accreditation organization and HCFA or its agents is acceptable only if this amount of disparity could have occurred by chance. The commenter stated that the proposed regulation does not provide enough information to assess whether a 20 percent rate of disparity would be statistically significant.

Response: It will be the responsibility of any accreditation organization seeking approval of deeming authority to develop and present the referenced crosswalk as part of its application package. It is acceptable for an accreditation organization to organize its requirements differently than HCFA does, and to have requirements that are not identical but are at least equivalent to Federal requirements. The accreditation organization must be able to provide reasonable assurance that all applicable Medicare conditions would be met. It will be HCFA's responsibility to determine if the accreditation organization's requirements as presented in its application are at least equivalent to HCFA's standards and are organized in such a way to enable HCFA to accept accreditation as providing reasonable assurance that all the Medicare conditions would be met.

In evaluating an accreditation organization's performance under validation review, HCFA will calculate a rate of disparity between the findings of the accreditation organization and the validation survey results. This calculation will be based on condition level deficiencies (or deficiencies in HCFA's requirements for long term care facilities) where the accreditation organization failed to identify the same or similar deficiencies. In addition, if an organization has received approval of an accreditation structure that is not exact in its replication of Medicare requirements, but which compensates in other areas so that its overall standards are at least equivalent to those established under the Act (for example, a lower constituent standard in one area of a condition level requirement is offset by a more stringent standard elsewhere in the requirements pertaining to the condition), HCFA will accommodate those distinctions in conducting validation surveys and in making conclusions with respect to the performance of accreditation organizations on the basis of the validation survey findings.

The 20 percent level of disparity that will be used in monitoring the effectiveness of accreditation organizations in providing reasonable assurance that accredited facilities meet Federal requirements is not indicative of an acceptable level of noncompliance with Federal requirements for accredited facilities. This figure was based on statistical analyses of historical validation survey findings for accredited hospitals for the period 1974 to 1991.

We cannot accept the comment that the use of a disparity rate be phased in or eliminated. As explained elsewhere, the 20 percent rate is simply a threshold that triggers a notice from HCFA to the accreditation organization that its deeming authority is in jeopardy and that its accreditation system is under rigorous scrutiny. Based on further evaluation, we could remove deeming authority, but the removal is not mandatory on the 20 percent criterion alone nor is a 20 percent rate of disparity an absolute requirement that must be met before HCFA can withdraw its approval of an accreditation organizations deeming authority. While deeming authority review will always be implemented when the rate of disparity is 20 percent or more, HCFA can institute such a review at any time validation findings indicate widespread or systematic problems in an organization's accreditation process that may indicate that there is no longer reasonable assurance that accredited entities meet Medicare requirements.

As stated earlier, an accreditation organization's approval period will not exceed a period of six years; we will conduct a validation review at the end of the term of approval. We reserve the right to determine if the reapplication process should occur more frequently than every six years. The frequency of the application and the nature of the reapplication materials will be based on a range of issues, such as:

An evaluation to determine if the accreditation organization follows its own procedures in imposing corrective action plans on providers and/or suppliers that do not meet its standards and in monitoring those plans with follow-up surveys.

An evaluation to determine if the accreditation organization is ensuring that identified deficiencies are corrected within the timeframes established in the organization's procedures.

An evaluation of whether deemed status is removed from those providers and suppliers that fail to correct their deficiencies in accordance with the established timeframes.

An evaluation to determine if the complaints are investigated timely and if onsite visits were required.

Paragraphs (d)(1)(iii) and (3) of § 488.8 now reflect the reapplication requirements.

Comment: One commenter stated that under § 488.9(c)(2)(i), the rate of disparity will not be needed if HCFA has the authority to impose termination or intermediate sanctions rather than removing deeming authority as an interim step.

Response: Section 488.9(c)(2)(i) of the proposed regulation (§ 488.8(d)(2)(i) in this final rule) refers to the term "rate of disparity" that applies strictly to the validation review process for accreditation organizations. The rate of disparity is used to determine if the removal of deeming authority from an organization is warranted. This provision does not, per se, refer to individual facilities. On the other hand, HCFA can remove deemed status from an individual facility whenever a condition level requirement is found out of compliance. HCFA has the authority to impose termination or intermediate sanctions at any time, based on its own survey findings or the survey findings of the accreditation organization.

Comment: Two commenters indicated that the calculation for determining the rate of disparity considers only deficiencies identified by HCFA that are not identified by the accreditation organization, effectively assuming that deficiencies identified by the accreditation organization, but not by HCFA, are irrelevant. They stated that State survey findings are the sole basis for judging the accreditation program findings, which assumes the validity

and reliability of the State agency surveys.

Response: In order to perform a comparative analysis of any kind, certain baseline standards must be established. Congress has charged HCFA with the authority to determine which requirements and standards are necessary for carrying out in good faith the laws related to the Medicare and Medicaid programs. Our validation program is concerned chiefly with the equivalency of accreditation standards to Federal requirements, and assuring that Medicare participating facilities deemed by virtue of accreditation would meet those requirements if surveyed against them. While it will be helpful for HCFA to examine its survey findings in light of deficiencies identified by accreditation organizations but not by HCFA, these findings have no place in evaluating the effectiveness of accreditation in satisfying existing Medicare requirements. We have clarified the definition of "rate of disparity" in § 488.1 to state more clearly that the calculation of the percentage rate is based on an organization's most recent surveys of providers or suppliers of the same type.

Comment: Four commenters stated that HCFA should define the phrase "significant reduction in the rate of disparity" in § 488.9(e)(iv)(B). One commenter indicated that § 488.9(c)(2)(i) mentions validation surveys and a disparity rate of 20 percent or more. The commenter questioned the use of a 20 percent "rate of disparity" to determine whether an accreditation organization meets requirements for retaining deeming authority. He stated that it is not uncommon to have differences in a validation survey, which upon review do not result in finding of significant noncompliance; perhaps, the issue could be clarified to specify the relative importance of various areas under review.

Response: As discussed previously, we have revised our approach to the use of validation review findings in evaluating the performance of accreditation organizations, and significant reduction in the rate of disparity will no longer be used. If an accreditation organization is subject to deeming authority review because its rate of disparity is 20 percent or more, its rate of disparity for validation review findings during the period of conditional approval must be reduced to less than 20 percent before it can be returned to unconditional approval status. If deeming authority review is undertaken on the basis of validation review findings where the rate of disparity was less than 20 percent, HCFA will make a determination, on the basis of its review, including review of recent validation findings, whether accreditation by the organization continues to provide reasonable assurance that the applicable Medicare requirements are met.

Comment: Two commenters suggested that the validation review required in § 488.9(c) should be replaced with the State Agency Evaluation Program (SAEP). They stated that SAEP uses a comprehensive approach in the evaluation of State survey agency performance. Another commenter indicated that the 1989 Federal monitoring surveys of unaccredited hospitals certified by State agencies for Medicare participation revealed that in this sample State agencies were judged to have had a 25 percent rate of disparity by Regional Office staff. The commenter believed that if a 25 percent rate of disparity is a reasonable performance standard for HCFA's own agents, it would seem a reasonable performance standard for accreditation organizations as well.

Response: The State agency evaluation program (SAEP) is a comprehensive evaluation protocol used in the administration of the contractual relationship between HCFA and the State survey agencies. The agreements between HCFA and the States are governed by Section 1864 of the Act as well as Federal and Departmental acquisition regulations, and the criteria used to evaluate accreditation organizations are not derivative of the SAEP. Therefore, it is inappropriate for us to act on this commenter's suggestion. We will continue to use the 20 percent rate stipulated in the proposed rule as a threshold indication that the accreditation organization is not meeting the regulatory requirements. The 20 percent rate will be the point at which HCFA will notify the organization that its approval for deeming authority is in jeopardy.

Comment: Six commenters stated that the rate of disparity and pattern of increasing disparity are discussed in relation to compliance with condition level deficiencies. The commenters believed that this is too permissive and leaves too many people at risk for too long a period of time, and that, further, it is based on condition level compliance, a construction not in use in nursing homes. They believed that this hierarchical approach would allow an accreditation organization to ignore, for example, inappropriate restraint use, inadequate social services, violations of residents' rights provision, inadequate activities, or improper nurse aide training to be tolerated indefinitely.

Response: We have revised our definition of "Medicare condition" at § 488.1 to include "long term care requirements"; therefore references to rates of disparity based on conditions include nursing home requirements. These requirements must be addressed in the crosswalk that organizations submit in their application for approval of deeming authority. A final rule pertaining to the requirements for long term care facilities eliminated the hierarchical system and the final enforcement rule allows the determination of the seriousness of deficiencies based on how far the nursing home deviates from HCFA's requirements. (See "BPD–396–F, Requirements for Long-Term Care Facilities" (56 FR 48826).) For other types of facilities, the hierarchial system of conditions, standards and elements is still in place. These conditions essentially represent clusters of standards, regardless of the type of facility accredited. Similarly, the accreditation organizations for these facilities must submit a crosswalk showing equivalency between their requirements and HCFA's clusters of standards. The evaluation of accreditation organizations' initial requests for deeming authority, as well as periodic validation and deeming authority reviews thereafter, provides continuing Federal oversight to assess the equivalency of the accreditation organization's standards to Federal requirements, including use of restraints, social services, residents' rights, etc.

Comment: One commenter recommended that both the triggering of a State agency survey and the provisions related to a deeming authority review should be based on determinations of a significant level of noncompliance with the requirements for participation for long term care facilities. The commenter further recommended that the definition of significant noncompliance be based on the citing of deficiencies and the imposition of a sanction or sanctions for a violation or violations that have resulted in negative outcomes, including the violation of residents' rights, causing actual or life-threatening harm or death; and/or based on the failure of the facility to meet administrative requirements to the degree that negative outcomes have occurred in sufficient number or with sufficient regularity.

Response: Now that the hierarchical system of nursing home requirements is eliminated, all requirements are equally enforceable. Therefore, deficiencies

with any requirements detected during a validation survey will be considered in computing the rate of disparity if comparable deficiencies were not detected by the accreditation survey.

Comment: One commenter believed that recognizing an accreditation organization under "deemed status" would result in duplicative staffing and a substantial increase in staff training for the State survey agencies.

Response: Under deemed status, the State agencies will continue to conduct surveys under the Federal requirements in effect for the facility type at the time of the survey. Inasmuch as the State agencies will conduct validation surveys only on a sample basis and in response to complaints, the granting of deemed status should not necessitate increased staffing levels or increased training needs at the State survey agencies.

Comment: One commenter requested that HCFA consider voluntary accreditation standards for the providers of rehabilitation services including rehabilitation agencies, comprehensive outpatient rehabilitation facilities, skilled nursing facilities, home health agencies, and public health agencies.

Response: We are not sure what the commenter means by "voluntary standards". Since accreditation organizations are not required to request approval for granting deemed status for various providers, any standards they develop are voluntary. However, the standards developed by accreditation organizations must be equivalent to HCFA's standards in order for the organization to receive approval to grant deemed status. Accreditation is also voluntary on the part of providers and suppliers. (Facilities can voluntarily choose to be accredited by an organization with deeming authority in lieu of having periodic certification surveys and ongoing monitoring by the State.) However, to be considered for deeming authority, an accreditation organization's standards must be requirements and, as such, may not be voluntary or optional. The provider/supplier categories mentioned by the commenter would be eligible for deemed status through means of accreditation if an accreditation organization applies for and receives approval of deeming authority.

Comment: Two commenters urged that the deeming authority review process be carried out in a rigorous and objective manner to ensure that quality of care will not be compromised.

Response: We agree with the commenters and believe that the review process set forth in § 488.9 insures a thorough and unbiased evaluation.

Comment: One commenter recommended that § 488.9 be revised to include the process for continued participation of a deemed facility when an accreditation organization loses its deeming authority. The commenter suggested two options: the first option would be to consider the facility as deemed until the expiration of its accreditation certificate even though the accreditation organization has lost its deeming authority; and the second option would be to include in the regulation a notice requirement to deemed facilities explaining that the accreditation organization has lost its deeming authority and informing the deemed facility of its options.

Response: Section 488.9 (now § 488.8) has been revised to add a paragraph that stipulates that facilities be notified of HCFA's removal of an accreditation organization's deeming authority, and the options available to each facility that had received deemed status based on its accreditation by that organization. Specifically, a provider's or supplier's deemed status will continue in effect for 60 days following notification and can be extended for an additional 60 days if we determine that the provider or supplier submitted a timely application to another approved accreditation organization or to us. A provider's or supplier's failure to do so will jeopardize its participation in the Medicare program and, where applicable, in the Medicaid program. These procedures will apply regardless of the provider's accreditation schedule to allow time for a State agency survey or accreditation by another approved organization.

Comment: Five commenters stated that the proposed rule establishes a prolonged process of negotiation when serious discrepancies exist due to lack of comparability between requirements and/or problems of poor performance. Further, one commenter believed there should be a continuum of sanctions including probation, suspension, termination and various forms of civil monetary penalties, depending on the degree of seriousness of the problem. The commenter believed that HCFA should not allow poor performance to continue for up to a year as is proposed nor allow protracted delays to occur before considering suspension of an organizations's deeming authority.

Response: HCFA only agrees to accept an approved accreditation organization's reasonable assurance that a deemed facility would meet HCFA's requirements if surveyed against them. HCFA has no statutory authority to impose sanctions on accreditation organizations, other than removal of deeming authority.

Section 488.8 sets forth two types of probationary periods. A probationary period of 180 days is provided when HCFA determines that an accreditation organization's standards are no longer equivalent to the applicable Federal requirements. This will allow a reasonable time for that organization to revise its standards to achieve equivalency with HCFA's requirements and to implement the revised standards. A probationary period of up to one year is provided when an accreditation organization's standards are determined to be equivalent to Federal requirements but the results of validation surveys indicate that the accreditation organization is incorrectly or inconsistently surveying for those requirements. This period of time is intended to provide the accreditation organization a reasonable opportunity to examine and improve its survey process and for HCFA to validate that the organization is once again surveying consistently with respect to its own requirements. For those facilities for which HCFA identifies deficiencies, the facilities' deemed status is removed and enforcement action can be taken immediately, regardless of the approval status of the accreditation organization.

The probationary periods provided for under deeming review do not apply, if at any time HCFA determines the continued approval of deeming authority of any accreditation organization poses an immediate jeopardy to the patients of the entities accredited by that organization, or such continued approval otherwise constitutes a significant hazard to the public health. In such cases, as provided in § 488.8(g), HCFA may immediately withdraw the approval of deeming authority of that accreditation organization. For example, if we determine, based on a validation review, comparability review, or an onsite visit to an approved accreditation organization, that the organization can no longer fulfill its obligation to perform surveys due to inadequate resources (e.g., financial hardship or lack of qualified personnel), we will institute measures to withdraw the approval of deeming authority immediately.

Comment: One commenter believed that the requirement in § 488.9 for 30 days' notice regarding changes in an organization's requirements is unduly burdensome. The commenter suggests that the rule be revised so that 30 days' advance notice is required only for changes that substantially affect an organization's accreditation standards

and not be required for checklist modifications.

Response: We cannot accept this recommendation because it is not administratively feasible to evaluate and sort each proposed change depending on the type or substance of the change.

Comment: One commenter stated that under § 488.9 the requirement to provide electronic data in ASCII equivalent code is meaningless without specification of format and other details. The commenter suggested the proposed rule should be modified to indicate that HCFA requires only "reasonably necessary information in an agreed upon computer-usable format necessary for validation and/or assessment of the organization's survey process."

Response: All references to ASCII code may be interpreted as the ability to generate Standard electronic data files that are capable of being processed on main frame computers. EBCDIC STANDARD 6250 BPI tape is an acceptable alternative to ASCII. File formats, record layouts, edits and procedures have not yet been designed. When these parameters are decided upon, we will require that they be submitted to HCFA electronically, either on magnetic tape or through electronic data transmission.

Comment: One commenter urged HCFA to specify in detail at § 488.9(a)(1)(ii)(A) the composition of the inspection team.

Response: We do not believe that this level of specificity in the regulation is warranted and, therefore, have not accepted this comment. In addition, these specific requirements will vary depending on the types of facilities for which the accreditation organization in seeking approval of deeming authority.

Comment: Two commenters suggested that when a facility is found, through a validation survey, to be out of compliance, the facility must be subject to the State survey requirements and may be subject to termination. The commenters argued that when HCFA removes the facility's deemed status and requires the facility to use HCFA's standards that it is an acknowledgement that the accreditation organization's standards are not equal to HCFA's standards.

Response: The issue of equivalent standards does not apply in this instance. An accreditation organization has the ability to survey a facility, but no authority to impose sanctions other than to withhold accreditation. When a facility is found to be out of compliance by the State survey agency, HCFA removes the facility's deemed status. Once the facility's deemed status is removed it is no longer under the accreditation body's standards and must meet HCFA's requirements. However, we will have found the accreditation organization's standards to provide reasonable assurance that Medicare conditions or requirements for long term care will be met. When HCFA evaluates the results of all validation surveys for a given accreditation organization, it may be that the organization's standards are no longer found to provide reasonable assurance that Medicare requirements are met. Similarly, HCFA may determine that the organization fails to demonstrate that it can consistently survey for its own standards. In either case, HCFA will take appropriate action under deeming authority review.

Comment: One commenter suggested that in § 488.9(a)(1)(ii)(B), which requires HCFA to review the organization's ability to investigate complaints, HCFA also be required to review the organization's ability to respond appropriately to them. The commenter also asked that the monitoring procedures an accreditation organization is proposing to use when a facility is out of compliance (required at § 488.9(a)(1)(ii)(C)) be developed and published.

Response: We accept the comment concerning the response to complaints and have revised the regulation accordingly. However, we do not believe we should require an accreditation organization to publish its procedures. By publishing a notice in the **Federal Register** that the organization's requirements are equivalent to ours, we are endorsing its monitoring procedures. Thus, we do believe it is unnecessarily burdensome to require the organization to publish these procedures.

Comment: Seven commenters believed that an administrative hearing process is absent from the proposed rule. The commenters believed that an administrative hearing process should be developed for accreditation organizations whose deeming authority applications are rejected or whose status is threatened with withdrawal of previously granted deeming authority.

Response: In response to this comment, we have revised the regulation to provide such a reconsideration process. We include a new subpart D in part 488 to provide a reconsideration for both denial of initial applications and withdrawal of deeming authority approval. The process described in subpart D affords the accreditation organization several opportunities to furnish information and evidence relative to the circumstances of the adverse action, including a hearing before a hearing officer.

Comment: Five commenters suggested that HCFA consider adding two additional criteria to the evaluation process for deemed authority applicants. The commenters suggested that experience with a specific type of provider be considered; the second criterion suggested was that the accreditation organization consult with professional associations. Two commenters further requested that a cost comparison per survey between accreditation organizations and State agencies be considered in evaluating the organization.

Response: We consider experience as part of the adequacy of staff and other resources in our evaluation of each accreditation organization's application for approval of deeming authority. We do not believe that consultation with professional associations should be part of the evaluation criteria since there is no direct link between an organization's standards equivalency to Federal requirements or survey performance and consultation with professional organizations. Finally, the costs incurred by an accreditation organization in conducting its surveys is immaterial to the deeming process, except as they relate to reimbursement by Medicare to individual facilities for the portion of accreditation fees allocable to the Medicare program. Accreditation fees determined to be not reasonable will be disallowed. We will also examine an organization's financial strength and commitment to the accreditation program to ensure that the organization can finance its surveys and related activities.

We have added a provision (§ 488.9, Onsite observation of accreditation organization operations) to the final rule that permits HCFA to conduct an onsite evaluation of the organization's accreditation operations, to verify information provided by the organization and to ensure that the organization follows its own policies and procedures. This observation may be in response to our review of an application or a validation review or as part of our continuing oversight of accreditation organizations.

Comment: Two commenters believed that efficient administration of the CLIA and Medicare programs requires the Secretary to establish consistent policies for the Federal review and approval of accreditation organizations seeking deeming authority for the purpose of laboratory compliance with CLIA and Medicare program conditions of participation and should be specifically addressed in the regulations so that

private accreditation organizations can be assured that inconsistent requirements under the two programs are efficiently resolved.

Response: We agree that the review of laboratory accreditation standards for deeming authority for both CLIA and Medicare requirements should be conducted in accordance with consistent policies. While these issues are addressed in separate regulations, the processes are essentially similar and singularly consistent. As discussed previously, CLIA laboratory requirements and Medicare laboratory requirements are one and the same. The approval process for deeming authority for laboratories, as opposed to other providers, was published in the July 31, 1992 rule (57 FR 33992).

Comment: We received five comments related to notice requirements. Two commenters recommended that under § 488.9(a)(1)(ii), which concerns the circumstances under which we will do a comparability review, a new section be added to read: "The ability of the organization to report deficiencies to the surveyed facility, and respond to the facility's plan of correction in a timely manner." The commenters believed that this revision is needed to achieve equivalency with Federal survey procedures. Three commenters asked that a paragraph be added in § 488.9 to require accreditation organizations to explain their procedures for notifying the State survey agency immediately when any serious problem exists that cannot be corrected in a very short period of time.

Response: We have revised proposed § 488.9(a)(1)(ii) (now § 488.8(a)(1)(ii)) to add a requirement that an accreditation organization must demonstrate its ability to report deficiencies to the surveyed facility. We do not believe it is necessary for an accreditation organization to notify the State agency of deficiencies in a facility, since the State agency is not authorized to take any action in these cases. Since HCFA will have access to all accreditation surveys, we can take necessary enforcement action on the basis of the accreditation survey.

Comment: Two commenters recommended that to the comparability of survey procedures in § 488.9(a)(ii)(B) we add a requirement that we review "the focus of the survey on resident outcomes; and the inclusion of procedures to assure survey consistency and surveyor accountability." The commenters believed that these additions are essential components of the survey currently included in the Federal survey procedures or anticipated through future OBRA survey and certification rulemaking.

Response: We have not accepted this comment. We believe that these proposed additions to the regulations are unnecessary because these issues are specifically evaluated in our initial review of an organization's application for approval of deeming authority and in our periodic review of deeming authority. Since a great number of the Medicare requirements and Federal survey procedures focus on patient outcomes and include provisions for surveyor consistency and accountability, an accreditation organization must demonstrate that its requirements focus on patient outcomes, as appropriate, that its survey process can consistently survey for those requirements on the basis of outcomes, and that the organization evaluates its surveyors and holds them accountable for their findings and performance.

Comment: Three commenters recommended that we revise § 488.9(a)(ii)(A), which requires us to determine the composition of the survey team, survey qualifications, and the ability of the organization to provide continuing surveyor training. The commenters wanted to add to these access to surveyor competency tests. The commenters indicated that a significant mandate of OBRA '87 toward achieving competency and consistency in the survey of nursing facilities is competency testing of surveyors. An equivalent test or demonstration of competency should be required of the accreditation organization's surveyors.

Response: The OBRA '87 requirement for continuing surveyor training and surveyor competency is a statutory requirement for nursing homes only and not a general requirement for all providers and suppliers. As we have stated earlier, each accreditation organization's standards must be equivalent to HCFA's participation requirements for the facility or facilities involved. The surveyor training and competency requirements are no exception and will be evaluated by HCFA.

Comment: One commenter stated that the proposed rule does not sufficiently articulate the procedures that accreditation organizations must follow in monitoring providers found not to be in compliance. The commenter suggested that HCFA should look at standards and elements as well as conditions.

Response: The proposed rule does not articulate any standards or procedures that accreditation organizations must follow. The concept of voluntary accreditation must provide an accreditation organization the opportunity to develop standards it believes will ensure the highest quality of care and services. When determining an organization's eligibility for deeming authority by means of accreditation, HCFA will evaluate the accreditation organization's standards and procedures to ascertain if they are at least equivalent to the Federal minimum requirements. An accreditation organization is expected to enforce its requirements rigorously whether they are organized based on standards and elements, or some other hierarchy.

Comment: Seven commenters stated that the criteria for actually qualifying to be approved as a deeming authority remain extremely general. The commenters urged HCFA to publish criteria for qualifications for approval as a deeming authority as a formal notice of proposed rulemaking with a minimum of a 60-day comment period.

Response: As with other statutory provisions for which HCFA is responsible, we have sought public comments on our interpretation of the statute and resulting regulatory policies. The provider-specific criteria mentioned by the commenter do not depend on statutory interpretation but on program policy, although the statute does stipulate some specific requirements from most providers and suppliers. To publish the qualifying criteria for each provider-type in the **Federal Register** to seek public comments would unnecessarily delay implementation of the regulation. We do recognize our responsibility to publish the general criteria, contained in § 488.9, and we also believe that the items that an accreditation organization must furnish in its application serve to define additional criteria.

Comment: One commenter recommended that specific criteria developed to evaluate accreditation organizations be applied by HCFA in evaluating its own survey process. The commenter believed that HCFA's guidelines are not specific and have no specific directions for translating findings into deficiencies.

Response: The criteria developed to evaluate accreditation organizations are based on Federal requirements. The evaluation criteria for the accreditation organization will be designed to determine whether an organization is capable of meeting HCFA's requirements. Using these evaluation criteria to evaluate HCFA's survey process serves no purpose since it is a tool to compare equivalency between the accreditation organization and HCFA. HCFA is continually evaluating the effectiveness of its survey programs

and implements enhancements to those programs at every opportunity. We have not accepted this comment.

Comment: Five commenters stated that the proposed rule at § 488.9(a)(1) (i) and (ii) should specify that the requirements and survey procedures be "equivalent" because all residents of certified nursing homes are entitled to the same protection under the Federal law. The commenters believed that since States are required to use HCFA's procedures, forms and guidelines that an accreditation organization must also use HCFA's procedures, forms and guidelines.

Response: HCFA will determine through its evaluation process whether an accreditation organization has equivalent requirements and acceptable survey procedures. HCFA will only approve accreditation organizations to grant deemed status to various providers if those accreditation organizations provide reasonable assurance that Medicare conditions, or requirements for long term care, will be met. We believe that when an accreditation organization's standards are found to be equivalent, those standards will provide the same protection to Medicare beneficiaries as HCFA requirements.

Comment: Eighteen commenters believed that § 488.9(a)(1)(i) is confusing as to what constitutes equivalent criteria. The commenters believed that the rule should specify the process used to determine equivalent standards.

Response: HCFA will use its provider-specific participation requirements and survey expertise to determine whether an accreditation organization has equivalent requirements. Specific criteria will be applied as necessary in making these determinations. We will not include provider-specific evaluation criteria in this rule for the following reasons:

- Evaluation criteria will be based on the participation requirements for each type of provider.
- Including this level of specificity limits HCFA's flexibility in evaluating accreditation organizations applying for the granting of deemed status, and limits the broad authority accorded to the Secretary to determine when accreditation provides reasonable assurance that Medicare requirements are met.
- This rule is a general rule to apply to all national accreditation organizations except those for laboratories. It is not intended to be an encyclopedic recapitulation of the various facility requirements, already specified elsewhere in our regulations.

Comment: Six commenters thought that allowing "equivalent" standards negates the public rulemaking process under the Administrative Procedure Act by allowing standard setting by accreditation organizations without public review and comment.

Response: The standard setting by the accreditation organization must be equivalent to HCFA participation requirements in order for HCFA to approve that organization to grant deemed status. Since the public has an opportunity to comment on all Federal participation requirements and those requirements are equal to any approved accreditation organization's requirements, the public has, in fact, had an opportunity to comment on the spirit of those requirements. Additionally, we do not believe that it would be appropriate to require an accreditation organization to seek public comments on its standards, although it may decide to do so on a voluntary basis. Therefore, we see no violation of the Administrative Procedure Act and have not revised our rule in this regard.

Comment: One commenter pointed out that in § 488.9(b) we state that facilities accredited by an approved accreditation organization are deemed to meet our conditions of participation except for those Federal conditions or standards which HCFA identifies as being more stringent or more precise than the requirements for accreditation. The commenter asked that those "more stringent" areas be specified in the final rule.

Response: We cannot specify in this rule any conditions or standards that HCFA identifies as being "more stringent" than the standards of any given accreditation organization. These areas will be identified through the application of provider-specific considerations in evaluating applications for approval of deeming authority. We do not believe that specifying conditions or requirements pertaining to different providers or suppliers in a general rule is appropriate. An accreditation organization's standards must be at least equivalent to Federal requirements for all condition-level requirements for which deeming authority is sought. Currently the only exceptions are the requirement for utilization review in all hospitals and the additional special staffing and medical records requirements that are necessary for the provision of active treatment in psychiatric hospitals. However, any participating hospital, accredited or unaccredited, can continue to meet the utilization review requirement as long as the hospital is subject to review by the appropriate utilization and quality control peer review organization. We have also revised the regulation to state more clearly that deeming authority is approved for a specific condition or conditions for each accreditation organization.

Comment: One commenter believed that HCFA's agents should not be permitted to use their standards to restrain others from providing services or practitioners from qualifying for positions that HCFA would allow them to fill. He stated that, for example, outside accreditation organizations should not be allowed to refuse recognition to physical therapy programs acceptable to HCFA nor should such a group be permitted to require laboratory directors with higher qualifications than HCFA recognizes.

Response: Seeking deemed status from an accreditation organization is strictly voluntary and does not affect any provider's or supplier's ability to participate in Medicare. An accreditation organization's standards must be equivalent but nothing prohibits the standards from being more stringent. We have no authority to restrict an accreditation organization's more stringent requirements.

Comment: One commenter asked that § 488.9(a)(1)(ii)(C) specify the types of providers for which this subsection applies. The commenters were unclear whether this provision applies to entities that sought but were denied accreditation or to entities that received accreditation and only later were found to be out of compliance with program requirements.

Response: This paragraph only speaks to areas which HCFA will evaluate when an accreditation organization is applying for deemed status. HCFA's evaluation of monitoring procedures is an assurance that when an accreditation organization finds noncompliance the organization has procedures to monitor those facilities appropriately. This provision applies to any and all of the providers or suppliers for which an accreditation organization seeks approval of deeming authority.

IV. Summary of Revisions

After review and consideration of comments, as described above, we are adopting as final the rule as proposed on December 14, 1990, except as follows:

A. To §§ 401.126(b)(2)(ii)(A) and 401.133(d), we add examples of enforcement actions that we may take and to which releasable information relates. We also add to §§ 401.126(b)(2)(i) and 401.133(d), for the sake of consistency, national accreditation organizations of laboratories meeting the requirements of

§ 493.506 to the entities to which the provisions of these paragraphs apply.

B. We change the provision in § 401.133(d) and (e) that allows us to release certain information so that it requires us to release it. In paragraph (e) we add a provision for consistency with paragraph (d) to be able to require a written request for home health agency surveys.

C. Section 488.1 is amended by adding a definition of "reasonable assurance" and we have revised the definitions of "accredited provider or supplier", "Medicare condition", "rate of disparity", "substantial allegation of noncompliance" and "validation review period".

D. We are updating statutory citations and regulation citations in § 488.3.

E. We add § 488.4 to specify application procedures.

F. In §§ 488.5 and 488.6, we are adding the State survey agency as an entity to which a hospital must authorize the release of its most recent survey (deleted from proposed § 488.7). We also provide for deeming status of providers and suppliers participating in the Medicaid program where applicable.

G. In § 488.6, we clarify that the requirements of an accreditation organization must be at least as stringent as HCFA's, when taken as a whole. We add to the list of accredited providers and suppliers in this section and in § 488.10 screening mammography services and rural primary care hospitals.

H. In § 488.7, we change "selective" sample to "representative sample", specify that the validation survey may be focused on a specific condition or conditions, and make technical changes. In paragraph (d), we specify that the requirements to which providers and suppliers will be subject are the participation and enforcement requirements and that they may be subject to applicable intermediate sanctions and remedies as well as termination of the provider agreement if applicable.

I. We are incorporating the contents of current § 488.8, Civil rights requirements, into § 489.10, Basic requirements [concerning provider and supplier agreements].

Section 489.10 currently requires providers and suppliers to agree to meet the civil rights requirements of 45 CFR parts 80, 84 and 90; § 488.8 requires surveyed providers and suppliers to meet the requirements of 45 CFR parts 80 and 84 and other pertinent requirements. Since § 488.8 in essence duplicates § 489.10, and we believe part 489 is a more logical place to impose civil rights requirements, we are revising § 489.10 to contain both the contents of current § 488.8 and § 489.10. We are also adding a description of the requirements of 45 CFR part 90 to the cross-reference to that section to match the descriptions of 45 CFR parts 80 and 84 currently in 42 CFR 488.8. 45 CFR part 90 prohibits discrimination on the basis of age.

J. In § 488.8 (proposed § 488.9) we include an accreditation organization's ability to (1) respond appropriately to complaints and (2) report deficiencies to the surveyed facility and respond to the facility's plan of correction in a timely manner as part of our evaluation and review of accreditation organizations. We clarify in § 488.8(b) what the notice we will publish will contain when an accrediting organization's application is approved. We revise paragraph (d)(2) so that an increasing rate of disparity over a two-year period will not be one of two mandatory triggers for a review; rather, any indication of decreasing performance may trigger a review. Paragraph (d)(1)(iii) adds the end of the approved term as a trigger for a comparability review; new paragraph (d)(3) adds reapplication procedures. New paragraph (e)(5) discusses submission of reapplication materials. In § 488.8(e)(4)(i) (designated as § 488.9(c)(4)(iv)(A) in the proposed rule), we specify that the results of an evaluation must indicate an acceptable rate of disparity instead of a significant reduction in the rate of disparity. We add two paragraphs, § 488.8(f)(8) and (9), to indicate our policy concerning continued deemed status of providers and suppliers if we remove our approval of an accreditation organization's deeming authority. We add a new paragraph (g) to permit immediate withdrawal of HCFA approval in cases involving immediate jeopardy to patients. We also make several technical clarifying changes.

K. We add a new § 488.9, Onsite observation of accreditation organization operations.

L. We also make a number of technical changes to conform the provisions of this rule to those of our rule concerning accreditation organizations for laboratories found in part 493.

M. We amend reconsideration procedures in subpart D of part 488 to include national accreditation organizations of entities other than laboratories.

V. Regulatory Impact Statement

A. Economic Impact

This rule does not, in itself, establish terms or conditions for Federal spending and does not impose any requirements that would precipitate changes in the conduct of private businesses. Inasmuch as the provisions of this rule could represent a striking departure from existing processes, it is impossible to gauge the impact of this rule with any precision, or to quantify any programmatic, budgetary, or economic impact. Nevertheless, our analyses of possible effects of this rule are detailed below.

Compliance with specific conditions and standards has always been required for certain health care providers and suppliers (e.g., hospitals, SNFs, HHAs) to establish eligibility for participation in the Medicare program. Currently, compliance with applicable requirements is established through an inspection and verification process, known as survey and certification, either directly by HCFA or by agencies of State government under an agreement with HCFA. However, hospitals can establish compliance either through routine survey and certification or through accreditation by the Joint Commission on the Accreditation of Healthcare Organizations (JCAHO) or the American Osteopathic Association (AOA). Accredited hospitals are deemed to meet Medicare requirements by virtue of their accreditation and are said to have deemed status. A decision to seek accreditation is voluntary on the part of each hospital; accreditation is never required for Medicare eligibility or participation. This rule expands the availability of deemed status to health care providers and suppliers other than hospitals if they are accredited by private organizations who apply for and receive approval of their accreditation programs.

Accreditation is an approval status conferred by an accrediting body and indicates that accredited member facilities meet the standards established by that body. Reminiscent of the long-standing tradition in the educational establishment, accreditation is perceived by many as a commitment on the part of the accredited entities to delivery of the highest quality services through voluntary adherence to requirements and standards that reflect sound policies and procedures, state of the art diagnostic and treatment strategies, and a philosophy that accents quality assurance. Accreditation programs not only set standards for their member facilities and assess their performance against those standards but also provide their members with educational and training programs, and technical assistance that may be necessary to meet their standards and enhance the quality of services

delivered. In certain cases, private insurance carriers reimburse accredited providers at higher rates than unaccredited ones, and, similarly, certain accreditation costs have historically been paid by the Medicare program.

The implementation of this rule and the subsequent availability of accreditation as an alternative to traditional survey and certification will afford a new flexibility to the health care provider community in determining how to most effectively and efficiently demonstrate compliance with Medicare requirements and establish eligibility for program reimbursement.

Currently, most of the costs of the survey and certification program are paid by the Federal government to State governmental agencies under the terms of a formal agreement. These State agencies perform onsite evaluations of compliance with Federal participation requirements and certify their findings to HCFA. HCFA also performs some survey activities directly, and the survey of special requirements for most psychiatric hospitals is performed by a private contractor.

The number and type of facilities surveyed by HCFA, its contractor and the State agencies as well as the available cost data are detailed below. The data are up-to-date as of 3/31/93.

Facility type	No. certified	Annual survey cost [1]
Medicare SNF	870	$13,749
SNF/NF [2]	10,226	14,793
Nonaccredited Hospital	1,330	[3] 8,450
JCAHO–AOA Accredited Hospital	5,107	.....
Psychiatric Hospital	720	10,450
Home Health Agency	6,596	4,590
Home visits [4]	.....	118
End-stage renal disease facility	2,362	2,809
Hospice	1,259	1,467
Screening Mammography [5]	6,639	450
All others [6]	4,824	1,489

[1] Reflects total survey and certification costs per facility including follow-up and complaint surveys and administrative costs. Costs are those reflected in Congressional budget projections for FY 1994.

[2] Dually participating Medicare skilled nursing facilities and Medicaid nursing facilities.

[3] Validation costs for JCAHO and AOA accredited hospitals are included: 5% of the accredited hospitals are surveyed as part of HCFA's validation program.

[4] Costs associated with surveyors' visits to homes of patients of HHAs.

[5] New provider category.

[6] All others include ambulatory surgery centers, rural health clinics, outpatient physical therapy, X-ray facilities and comprehensive outpatient rehabilitation facilities.

There are two major variables associated with the implementation of this rule that preclude any projected impact assessment: First, the number of accreditation organizations that will apply for and receive approval of deeming authority; and second, the number of each facility type that will avail themselves of the accreditation alternative.

There is no direct statutory authority for deemed status under the Medicaid program. Therefore, it is extremely unlikely that certain dually participating facilities, especially SNFs/NFs, would seek to demonstrate compliance through accreditation since that would double the number of surveys performed in the facility. Specifically, a dually participating SNF/NF could be subject to both an accreditation survey that could be used to satisfy Medicare requirements and a State agency survey to determine compliance with Medicaid requirements.

No substantial economic or budgetary impact is expected as a result of this rule. Federal expenditures to ensure compliance with requirements will continue either in payments to States to perform compliance surveys or to facilities in reimbursement for the reasonable and allocable accreditation costs for cost reimbursed facilities or as reflected in a facility's payment rates when paid under another mechanism (for example, the prospective payment system).

B. Regulatory Flexibility Act

We generally prepare a regulatory flexibility analysis that is consistent with the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 through 612) unless the Secretary certifies that a rule does not have a significant economic impact on a substantial number of small entities. As discussed above, we believe that the provisions of this regulation do not, in themselves, have an economic impact. Indirectly, this rule may result in future issuances whereby small entities might be affected. However, in each of these cases, procedures consistent with the RFA will be followed and a regulatory flexibility analysis performed, if warranted. Therefore, we conclude, and the Secretary certifies, that this rule does not have a significant economic impact on a substantial number of small entities.

C. Rural Hospital Impact Statement

Section 1102(b) of the Act requires the Secretary to prepare a regulatory impact analysis if a rule may have significant impact on the operations of a substantial number of small rural hospitals. Such an analysis must conform to the provisions of section 604 of RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital with fewer than 50 beds located outside of a Metropolitan Statistical Area.

We are not preparing a rural impact statement since we have determined, and the Secretary certifies, that this rule, in itself, does not have a significant economic impact on the operations of a substantial number of small rural hospitals.

VI. Paperwork Burden

These changes do not impose paperwork collection requirements. Consequently, they need not be reviewed by the Executive Office of Management and Budget under the authority of the Paperwork Reduction Act of 1980 (44 U.S.C. 3801 *et seq.*).

List of Subjects

42 CFR Part 401

Claims, Freedom of information, Health facilities, Medicare, Privacy.

42 CFR Part 488

Health facilities, Survey and certification, Forms and guidelines.

42 CFR Part 489

Health facilities, Medicare, Reporting and recordkeeping requirements.

42 CFR chapter IV is amended as follows:

A. Part 401, subpart B is amended as follows:

PART 401—GENERAL ADMINISTRATIVE REQUIREMENTS

1. The authority citation is revised to read as follows:

Authority: Secs. 205, 1102, 1106, 1865 and 1871 of the Social Security Act (42 U.S.C. 405, 1302, 1306, 1395bb and 1395hh); the Freedom of Information Act (5 U.S.C. 552); and the Privacy Act (5 U.S.C. 552a).

2. Paragraph (b)(2) of § 401.126 is revised to read as follows:

§ 401.126 Information or records that are not available.

* * * * *

(b) *Materials exempt from disclosure by statute.*

(1) * * *

(2)(i) Except as specified in paragraph (b)(2)(ii) of this section, HCFA may not disclose any accreditation survey or any

information directly related to the survey (including corrective action plans) made by and released to it by the Joint Commission on Accreditation of Healthcare Organizations, the American Osteopathic Association or any other national accreditation organization that meets the requirements of § 488.6 or § 493.506 of this chapter. Materials that are confidential include accreditation letters and accompanying recommendations and comments prepared by an accreditation organization concerning the entities it surveys.

(ii) *Exceptions.*

(A) HCFA may release the accreditation survey of any home health agency; and

(B) HCFA may release the accreditation survey and other information directly related to the survey (including corrective action plans) to the extent the survey and information relate to an enforcement action (for example, denial of payment for new admissions, civil money penalties, temporary management and termination) taken by HCFA; and

* * * * *

3. In § 401.133, the introductory text is republished, the section heading is revised and the section is amended by adding new paragraphs (d) and (e) to read as follows:

§ 401.133 Availability of official reports on providers and suppliers of services, State agencies, intermediaries, and carriers under Medicare.

The following shall be made available to the public under the conditions specified:

* * * * *

(d) *Accreditation surveys.* Upon written request, HCFA will release the accreditation survey and related information from an accreditation organization meeting the requirements of § 488.5, § 488.6 or § 493.506 of this chapter to the extent the survey and information relate to an enforcement action taken (for example, denial of payment for new admission, civil money penalties, temporary management and termination) by HCFA;

(e) Upon written request, HCFA will release the accreditation survey of any home health agency.

PART 488—SURVEY AND CERTIFICATION PROCEDURES

B. Part 488 is amended as follows:

1. The authority citation is revised to read as follows:

Authority: Secs. 1102, 1138(b), 1814, 1819, 1832, 1861, 1864, 1865, 1866, 1871, 1880, 1881, 1883, and 1919 of the Social Security Act (42 U.S.C. 1302, 1320b–5(b), 1395f, 1395i–3, 1395k, 1395x, 1395aa, 1395bb, 1395cc, 1395hh, 1395qq, 1395rr, 1395tt, and 1396r).

2. Section 488.1 is amended by revising the definition of "Substantial allegation", removing "Accredited hospital", and adding definitions for "Accredited provider or supplier", "Conditions for coverage", "Conditions of participation", "Medicare condition", "Rate of disparity", "Reasonable assurance", and "Validation review period" to read as follows:

§ 488.1 Definitions.

As used in this part—

Accredited provider or supplier means a provider or supplier that has voluntarily applied for and has been accredited by a national accreditation program meeting the requirements of and approved by HCFA in accordance with § 488.5 or § 488.6.

* * * * *

Conditions for coverage means the requirements suppliers must meet to participate in the Medicare program.

Conditions of participation means the requirements providers other than skilled nursing facilities must meet to participate in the Medicare program and includes conditions of certification for rural health clinics.

* * * * *

Medicare condition means any condition of participation or for coverage, including any long term care requirements.

* * * * *

Rate of disparity means the percentage of all sample validation surveys for which a State survey agency finds noncompliance with one or more Medicare conditions and no comparable condition level deficiency was cited by the accreditation organization, where it is reasonable to conclude that the deficiencies were present at the time of the accreditation organization's most recent surveys of providers or suppliers of the same type.

Example: Assume that during a validation review period State survey agencies perform validation surveys at 200 facilities of the same type (for example, ambulatory surgical centers, home health agencies) accredited by the same accreditation organization. The State survey agencies find 60 of the facilities out of compliance with one or more Medicare conditions, and it is reasonable to conclude that these deficiencies were present at the time of the most recent survey by an accreditation organization. The accreditation organization, however, has found deficiencies comparable to the condition level deficiencies at only 22 of the 60 facilities. These validation results would yield ((60–22)/200) a rate of disparity of 19 percent.

Reasonable assurance means that an accreditation organization has demonstrated to HCFA's satisfaction that its requirements, taken as a whole, are at least as stringent as those established by HCFA, taken as a whole.

* * * * *

Substantial allegation of noncompliance means a complaint from any of a variety of sources (including complaints submitted in person, by telephone, through written correspondence, or in newspaper or magazine articles) that, if substantiated, would affect the health and safety of patients and raises doubts as to a provider's or supplier's noncompliance with any Medicare condition.

* * * * *

Validation review period means the one year period during which HCFA conducts a review of the validation surveys and evaluates the results of the most recent surveys performed by the accreditation organization.

3. In § 488.3, the section heading is revised, the introductory paragraph (a) is republished and paragraphs (a)(1) and (a)(2) are revised to read as follows:

§ 488.3 Conditions of participation; conditions for coverage; and long-term care requirements.

(a) *Basic rules.* In order to be approved for participation in or coverage under the Medicare program, a prospective provider or supplier must—

(1) Meet the applicable statutory definition in section 1138(b), 1819, 1832(a)(2)(F), 1861, 1881, or 1919 of the Act; and

(2) Be in compliance with the applicable conditions or long-term care requirements prescribed in subpart N, Q or U of part 405, part 416, subpart C of part 418, part 482, part 483, part 484, part 485, subpart A of part 491, or part 494 of this chapter.

* * * * *

4. A new § 488.4 is added to read as follows:

§ 488.4 Application and reapplication procedures for accreditation organizations.

(a) A national accreditation organization applying for approval of deeming authority for Medicare requirements under § 488.5 or 488.6 of this subpart must furnish to HCFA the information and materials specified in paragraphs (a)(1) through (10) of this section. A national accreditation organization reapplying for approval must furnish to HCFA whatever information and materials from

paragraphs (a)(1) through (10) of this section that HCFA requests. The materials and information are—

(1) The types of providers and suppliers for which the organization is requesting approval;

(2) A detailed comparison of the organization's accreditation requirements and standards with the applicable Medicare requirements (for example, a crosswalk);

(3) A detailed description of the organization's survey process, including—

(i) Frequency of the surveys performed;

(ii) Copies of the organization's survey forms, guidelines and instructions to surveyors;

(iii) Accreditation survey review process and the accreditation status decision-making process;

(iv) Procedures used to notify accredited facilities of deficiencies and the procedures used to monitor the correction of deficiencies in accredited facilities; and

(v) Whether surveys are announced or unannounced;

(4) Detailed information about the individuals who perform surveys for the accreditation organization, including—

(i) The size and composition of accreditation survey teams for each type of provider and supplier accredited;

(ii) The education and experience requirements surveyors must meet;

(iii) The content and frequency of the in-service training provided to survey personnel;

(iv) The evaluation systems used to monitor the performance of individual surveyors and survey teams; and

(v) Policies and procedures with respect to an individual's participation in the survey or accreditation decision process of any facility with which the individual is professionally or financially affiliated;

(5) A description of the organization's data management and analysis system with respect to its surveys and accreditation decisions, including the kinds of reports, tables, and other displays generated by that system;

(6) The organization's procedures for responding to and for the investigation of complaints against accredited facilities, including policies and procedures regarding coordination of these activities with appropriate licensing bodies and ombudsmen programs;

(7) The organization's policies and procedures with respect to the withholding or removal of accreditation status for facilities that fail to meet the accreditation organization's standards or requirements, and other actions taken by the organization in response to noncompliance with its standards and requirements;

(8) A description of all types (for example, full, partial, type of facility, etc.) and categories (provisional, conditional, temporary, etc.) of accreditation offered by the organization, the duration of each type and category of accreditation and a statement specifying the types and categories of accreditation for which approval of deeming authority is sought;

(9) A list of all currently accredited facilities, the type and category of accreditation currently held by each facility, and the expiration date of each facility's current accreditation; and

(10) A list of all full and partial accreditation surveys scheduled to be performed by the organization.

(b) The accreditation organization must also submit the following supporting documentation—

(1) A written presentation that demonstrates the organization's ability to furnish HCFA with electronic data in ASCII comparable code;

(2) A resource analysis that demonstrates that the organization's staffing, funding and other resources are adequate to perform the required surveys and related activities; and

(3) A statement acknowledging that as a condition for approval of deeming authority, the organization will agree to—

(i) Notify HCFA in writing of any facility that has had its accreditation revoked, withdrawn, or revised, or that has had any other remedial or adverse action taken against it by the accreditation organization within 30 days of any such action taken;

(ii) Notify all accredited facilities within 10 days of HCFA's withdrawal of the organization's approval of deeming authority;

(iii) Notify HCFA in writing at least 30 days in advance of the effective date of any proposed changes in accreditation requirements;

(iv) Within 30 days of a change in HCFA requirements, submit to HCFA an acknowledgement of HCFA's notification of the change as well as a revised crosswalk reflecting the new requirements and inform HCFA about how the organization plans to alter its requirements to conform to HCFA's new requirements;

(v) Permit its surveyors to serve as witnesses if HCFA takes an adverse action based on accreditation findings;

(vii) Notify HCFA in writing within ten days of a deficiency identified in any accreditation entity where the deficiency poses an immediate jeopardy to the entity's patients or residents or a hazard to the general public; and

(viii) Conform accreditation requirements to changes in Medicare requirements.

(c) If HCFA determines that additional information is necessary to make a determination for approval or denial of the accreditation organization's application for deeming authority, the organization will be notified and afforded an opportunity to provide the additional information.

(d) HCFA may visit the organization's offices to verify representations made by the organization in its application, including, but not limited to, review of documents and interviews with the organization's staff.

(e) The accreditation organization will receive a formal notice from HCFA stating whether the request for deeming authority has been approved or denied, the rationale for any denial, and reconsideration and reapplication procedures.

(f) An accreditation organization may withdraw its application for approval of deeming authority at any time before the formal notice provided for in paragraph (e) of this section is received.

(g) Except as provided in paragraph (i) of this section, an accreditation organization that has been notified that its request for deeming authority has been denied may request a reconsideration of that determination in accordance with subpart D of this part.

(h) Except as provided in paragraph (i) of this section, any accreditation organization whose request for approval of deeming authority has been denied may resubmit its application if the organization—

(1) Has revised its accreditation program to address the rationale for denial of its previous request;

(2) Can demonstrate that it can provide reasonable assurance that its accredited facilities meet applicable Medicare requirements; and

(3) Resubmits the application in its entirety.

(i) If an accreditation organization has requested, in accordance with part 488, subpart D of this chapter, a reconsideration of HCFA's determination that its request for deeming approval is denied, it may not submit a new application for deeming authority for the type of provider or supplier that is at issue in the reconsideration until the reconsideration is administratively final.

5. Section 488.5 is revised to read as follows:

§ 488.5 Effect of JCAHO or AOA accreditation of hospitals.

(a) *Deemed to meet.* Institutions accredited as hospitals by the JCAHO or AOA are deemed to meet all of the Medicare conditions of participation for hospitals, except—

(1) The requirement for utilization review as specified in section 1861(e)(6) of the Act and in § 482.30 of this chapter;

(2) The additional special staffing and medical records requirements that are considered necessary for the provision of active treatment in psychiatric hospitals (section 1861(f) of the Act) and implementing regulations; and

(3) Any requirements under section 1861(e) of the Act and implementing regulations that HCFA, after consulting with JCAHO or AOA, identifies as being higher or more precise than the requirements for accreditation (section 1865(a)(4) of the Act).

(b) *Deemed status for providers and suppliers that participate in the Medicaid program.* Eligibility for Medicaid participation can be established through Medicare deemed status for providers and suppliers that are not required under Medicaid regulations to comply with any requirements other than Medicare participation requirements for that provider or supplier type.

(c) *Release and use of hospital accreditation surveys.*

(1) A hospital deemed to meet program requirements must authorize its accreditation organization to release to HCFA and the State survey agency a copy of its most current accreditation survey together with any other information related to the survey that HCFA may require (including corrective action plans).

(2) HCFA may use a validation survey, an accreditation survey or other information related to the survey to determine that a hospital does not meet the Medicare conditions of participation.

(3) HCFA may disclose the survey and information related to the survey to the extent that the accreditation survey and related survey information are related to an enforcement action taken by HCFA.

6. Section 488.6 is redesignated as § 488.7 and is revised to read as follows:

§ 488.7 Validation survey.

(a) *Basis for survey.* HCFA may require a survey of an accredited provider or supplier to validate its organization's accreditation process. These surveys will be conducted on a representative sample basis, or in response to substantial allegations of noncompliance.

(1) When conducted on a representative sample basis, the survey is comprehensive and addresses all Medicare conditions or is focused on a specific condition or conditions.

(2) When conducted in response to a substantial allegation, the State survey agency surveys for any condition that HCFA determines is related to the allegations.

(3) If the State survey agency substantiates a deficiency and HCFA determines that the provider or supplier is out of compliance with any Medicare condition, the State survey agency conducts a full Medicare survey.

(b) *Effect of selection for survey.* A provider or supplier selected for a validation survey must—

(1) Authorize the validation survey to take place; and

(2) Authorize the State survey agency to monitor the correction of any deficiencies found through the validation survey.

(c) *Refusal to cooperate with survey.* If a provider or supplier selected for a validation survey fails to comply with the requirements specified in paragraph (b) of this section, it will no longer be deemed to meet the Medicare conditions but will be subject to full review by the State survey agency in accordance with § 488.11 and may be subject to termination of its provider agreement under § 489.53 of this chapter.

(d) *Consequences of finding of noncompliance.* If a validation survey results in a finding that the provider or supplier is out of compliance with one or more Medicare conditions, the provider or supplier will no longer be deemed to meet any Medicare conditions. Specifically, the provider or supplier will be subject to the participation and enforcement requirements applied to all providers or suppliers that are found out of compliance following a State agency survey under § 488.24 and to full review by a State agency survey in accordance with § 488.11 and may be subject to termination of the provider agreement under § 439.53 of this chapter and any other applicable intermediate sanctions and remedies.

(e) *Reinstating effect of accreditation.* An accredited provider or supplier will again be deemed to meet the Medicare conditions in accordance with this section if—

(1) It withdraws any prior refusal to authorize its accreditation organization to release a copy of the provider's or supplier's current accreditation survey;

(2) It withdraws any prior refusal to allow a validation survey; and

(3) HCFA finds that the provider or supplier meets all the applicable Medicare conditions. If HCFA finds that an accredited facility meets the Life Safety Code Standard by virtue of a plan of correction, the State survey agency will continue to monitor the facility until it is in compliance with the Life Safety Code Standard.

7. A new § 488.6 is added to read as follows:

§ 488.6 Other national accreditation programs for hospitals and other providers and suppliers.

(a) In accordance with the requirements of this subpart, a national accreditation program for hospitals; psychiatric hospitals; SNFs; HHAs; ASCs; RHCs; CORFs; hospices; screening mammography services; rural primary care hospitals; or clinic, rehabilitation agency, or public health agency providers of outpatient physical therapy, occupational therapy or speech pathology services may provide reasonable assurance to HCFA that it requires the providers or suppliers it accredits to meet requirements that are at least as stringent as the Medicare conditions when taken as a whole. In such a case, HCFA may deem the providers or suppliers the program accredits to be in compliance with the appropriate Medicare conditions. These providers and suppliers are subject to validation surveys under § 488.7 of this subpart. HCFA will publish notices in the **Federal Register** in accordance with § 488.8(b) identifying the programs and deeming authority of any national accreditation program and the providers or suppliers it accredits. The notice will describe how the accreditation organization's accreditation program provides reasonable assurance that entities accredited by the organization meet Medicare requirements. (See § 488.5 for requirements concerning hospitals accredited by JCAHO or AOA.)

(b) Eligibility for Medicaid participation can be established through Medicare deemed status for providers and suppliers that are not required under Medicaid regulations to comply with any requirements other than Medicare participation requirements for that provider or supplier type.

(c)(1) A provider or supplier deemed to meet program requirements under paragraph (a) of this section must authorize its accreditation organization to release to HCFA and the State survey agency a copy of its most current accreditation survey, together with any information related to the survey that HCFA may require (including corrective action plans).

(2) HCFA may determine that a provider or supplier does not meet the Medicare conditions on the basis of its own investigation of the accreditation survey or any other information related to the survey.

(3) Upon written request, HCFA may disclose the survey and information related to the survey—

(i) Of any HHA; or

(ii) Of any other provider or supplier specified at paragraph (a) of this section if the accreditation survey and related survey information relate to an enforcement action taken by HCFA.

8. Section 488.8 is revised to read as follows:

§ 488.8 Federal review of accreditation organizations.

(a) *Review and approval of national accreditation organization.* HCFA's review and evaluation of a national accreditation organization will be conducted in accordance with, but will not necessarily be limited to, the following general criteria—

(1) The equivalency of an accreditation organization's accreditation requirements of an entity to the comparable HCFA requirements for the entity;

(2) The organization's survey process to determine—

(i) The composition of the survey team, surveyor qualifications, and the ability of the organization to provide continuing surveyor training;

(ii) The comparability of survey procedures to those of State survey agencies, including survey frequency, and the ability to investigate and respond appropriately to complaints against accredited facilities;

(iii) The organization's procedures for monitoring providers or suppliers found by the organization to be out of compliance with program requirements. These monitoring procedures are to be used only when the organization identifies noncompliance. If noncompliance is identified through validation surveys, the State survey agency monitors corrections as specified at § 488.7(b)(3);

(iv) The ability of the organization to report deficiencies to the surveyed facilities and respond to the facility's plan of correction in a timely manner;

(v) The ability of the organization to provide HCFA with electronic data in ASCII comparable code and reports necessary for effective validation and assessment of the organization survey process;

(vi) The adequacy of staff and other resources;

(vii) The organization's ability to provide adequate funding for performing required surveys; and

(viii) The organization's policies with respect to whether surveys are announced or unannounced; and

(3) The accreditation organization's agreement to provide HCFA with a copy of the most current accreditation survey together with any other information related to the survey as HCFA may require (including corrective action plans).

(b) *Notice and comment.*

(1) HCFA will publish a proposed notice in the **Federal Register** whenever it contemplates approving an accreditation organization's application for deeming authority. The proposed notice will specify the basis for granting approval of deeming authority and the types of providers and suppliers accredited by the organization for which deeming authority would be approved. The proposed notice will also describe how the accreditation organization's accreditation program provides reasonable assurance that entities accredited by the organization meet Medicare requirements. The proposed notice will also provide opportunity for public comment.

(2) HCFA will publish a final notice in the **Federal Register** whenever it grants deeming authority to a national accreditation organization. Publication of the final notice will follow publication of the proposed notice by at least six months. The final notice will specify the effective date of the approval of deeming authority and the term of approval (which will not exceed six years).

(c) *Effects of approval of an accreditation organization.* HCFA will deem providers and suppliers accredited by an approved accreditation organization to meet the Medicare conditions for which the approval of deeming authority has specifically been granted. The deeming authority will take effect 90 days following the publication of the final notice.

(d) *Continuing Federal oversight of equivalency of an accreditation organization and removal of deeming authority.* This paragraph establishes specific criteria and procedures for continuing oversight and for removing the approval of deeming authority of a national accreditation organization.

(1) *Comparability review.* HCFA will compare the equivalency of an accreditation organization's accreditation requirements to the comparable HCFA requirements if—

(i) HCFA imposes new requirements or changes its survey process;

(ii) An accreditation organization proposes to adopt new requirements or change its survey process. An accreditation organization must provide written notification to HCFA at least 30 days in advance of the effective date of any proposed changes in its accreditation requirements or survey process; and

(iii) An accreditation organization's approval has been in effect for the maximum term specified by HCFA in the final notice.

(2) *Validation review.* Following the end of a validation review period, HCFA will identify any accreditation programs for which—

(i) Validation survey results indicate a rate of disparity between certifications of the accreditation organization and certification of the State agency of 20 percent or more; or

(ii) Validation survey results, irrespective of the rate of disparity, indicate widespread or systematic problems in an organization's accreditation process that provide evidence that there is no longer reasonable assurance that accredited entities meet Medicare requirements.

(3) *Reapplication procedures.*

(i) Every six years, or sooner as determined by HCFA, an approved accreditation organization must reapply for continued approval of deeming authority. HCFA will notify the organization of the materials the organization must submit as part of the reapplication procedure.

(ii) An accreditation organization that is not meeting the requirements of this subpart, as determined through a comparability review, must furnish HCFA, upon request and at any time, with the reapplication materials HCFA requests. HCFA will establish a deadline by which the materials are to be submitted.

(e) *Notice.* If a comparability or validation review reveals documentation that an accreditation organization is not meeting the requirements of this subpart, HCFA will provide written notice to the organization indicating that its deeming authority approval may be in jeopardy and that a deeming authority review is being initiated. The notice provides the following information—

(1) A statement of the requirements, instances, rates or patterns of discrepancies that were found as well as other related documentation;

(2) An explanation of HCFA's deeming authority review on which the final determination is based;

(3) A description of the process available if the accreditation organization wishes an opportunity to explain or justify the findings made during the comparability or validation review;

(4) A description of the possible actions that may be imposed by HCFA based on the findings from the validation review; and

(5) The reapplication materials the organization must submit and the deadline for their submission.

(f) *Deeming authority review.*

(1) HCFA will conduct a review of an accreditation organization's accreditation program if the comparability or validation review produces findings as described at paragraph (d)(1) or (2), respectively, of this section. HCFA will review as appropriate either or both—

(i) The requirements of the accreditation organization; or

(ii) The criteria described in paragraph (a)(1) of this section to reevaluate whether the accreditation organization continues to meet all these criteria.

(2) If HCFA determines, following the deeming authority review, that the accreditation organization has failed to adopt requirements comparable to HCFA's or submit new requirements timely, the accreditation organization may be given a conditional approval of its deeming authority for a probationary period of up to 180 days to adopt comparable requirements.

(3) If HCFA determines, following the deeming authority review, that the rate of disparity identified during the validation review meets either of the criteria set forth in paragraph (d)(2) of this section HCFA—

(i) May give the accreditation organization conditional approval of its deeming authority during a probationary period of up to one year (whether or not there are also noncomparable requirements) that will be effective 30 days following the date of this determination;

(ii) Will require the accreditation organization to release to HCFA upon its request any facility-specific data that is required by HCFA for continued monitoring;

(iii) Will require the accreditation organization to provide HCFA with a survey schedule for the purpose of intermittent onsite monitoring by HCFA staff, State surveyors, or both; and

(iv) Will publish in the Medicare Annual Report to Congress the name of any accreditation organization given a probationary period by HCFA.

(4) Within 60 days after the end of any probationary period, HCFA will make a final determination as to whether or not an accreditation program continues to meet the criteria described at paragraph (a)(1) of this section and will issue an appropriate notice (including reasons for the determination) to the accreditation organization and affected providers or suppliers. This determination will be based on any of the following—

(i) The evaluation of the most current validation survey and review findings. The evaluation must indicate an acceptable rate of disparity of less than 20 percent between the certifications of the accreditation organization and the certifications of the State agency as described at paragraph (d)(2)(i) of this section in order for the accreditation organization to retain its approval;

(ii) The evaluation of facility-specific data, as necessary, as well as other related information;

(iii) The evaluation of an accreditation organization's surveyors in terms of qualifications, ongoing training composition of survey team, etc.;

(iv) The evaluation of survey procedures; or

(v) The accreditation requirements.

(5) If the accreditation program has not made improvements acceptable to HCFA during the probationary period, HCFA may remove recognition of deemed authority effective 30 days from the date that it provides written notice to the organization that its deeming authority will be removed.

(6) The existence of any validation review, deeming authority review, probationary period, or any other action by HCFA, does not affect or limit the conducting of any validation survey.

(7) HCFA will publish a notice in the **Federal Register** containing a justification of the basis for removing the deeming authority from an accreditation organization. The notice will provide the reasons the accreditation organization's accreditation program no longer meets Medicare requirements.

(8) After HCFA removes approval of an accreditation organization's deeming authority, an affected provider's or supplier's deemed status continues in effect 60 days after the removal of approval. HCFA may extend the period for an additional 60 days for a provider or supplier if it determines that the provider or supplier submitted an application within the initial 60 day timeframe to another approved accreditation organization or to HCFA so that a certification of compliance with Medicare conditions can be determined.

(9) Failure to comply with the timeframe requirements specified in paragraph (f)(8) of this section will jeopardize a provider's or supplier's participation in the Medicare program and where applicable in the Medicaid program.

(g) If at any time HCFA determines that the continued approval of deeming authority of any accreditation organization poses an immediate jeopardy to the patients of the entities accredited by that organization, or such continued approval otherwise constitutes a significant hazard to the public health; HCFA may immediately withdraw the approval of deeming authority of that accreditation organization.

(h) Any accreditation organization dissatisfied with a determination to remove its deeming authority may request a reconsideration of that determination in accordance with subpart D of this part.

9. Section 488.9 is added to read as follows:

§ 488.9 Onsite observation of accreditation organization operations.

As part of the application review process, the validation review process, or the continuing oversight of an accreditation organization's performance, HCFA may conduct an onsite inspection of the accreditation organization's operations and offices to verify the organization's representations and to assess the organization's compliance with its own policies and procedures. The onsite inspection may include, but is not limited to, the review of documents, auditing meetings concerning the accreditation process, the evaluation of survey results or the accreditation decision-making process, and interviews with the organization's staff.

10. Section 488.10(d) is revised to read as follows:

§ 488.10 State survey agency review; Statutory provisions.

* * * * *

(d) Section 1865(a) of the Act also provides that if HCFA finds that accreditation of a hospital; psychiatric hospital; SNF; HHA; hospice; ASC; RHC; CORF; laboratory; screening mammography service; rural primary care hospital; or clinic, rehabilitation agency, or public health agency provider of outpatient physical therapy, occupational therapy, or speech pathology services by any national accreditation organization provides reasonable assurance that any or all Medicare conditions are met, HCFA may treat the provider or supplier as meeting the conditions.

§ 488.11 [Amended]

11. In § 488.11(b), the reference to § 488.6 is revised to read "§ 488.7."

12. Section 488.201(a)(1) is revised to read as follows:

§ 488.201 Reconsideration.

(a) *Right to reconsideration.* (1) A national accreditation organization dissatisfied with a determination that its accreditation requirements do not provide (or do not continue to provide) reasonable assurance that the entities accredited by the accreditation organization meet the applicable long-term care requirements, conditions for coverage, conditions of certification, conditions of participation, or CLIA condition level requirements is entitled to a reconsideration as provided in this subpart.

* * * * *

C. Part 489 is amended as follows:

PART 489—PROVIDER AND SUPPLIER AGREEMENTS

1. The authority citation continues to read as follows:

Authority: Secs. 1102, 1861, 1864, 1866, and 1871 of the Social Security Act (42 U.S.C. 1302, 1395x, 1395aa, 1395cc, and 1395hh).

2. Section 489.10 is revised to read as follows:

§ 489.10 Basic requirements.

(a) Any of the providers specified in § 489.2 may request participation in Medicare. In order to be accepted, it must meet the conditions of participation or requirements (for SNFs) set forth in this section and elsewhere in this chapter.

(b) In order to participate in the Medicare program, the provider must meet the requirements of:

(1) Title VI of the Civil Rights Act of 1964, as implemented by 45 CFR part 80, which provides that no person in the United States shall, on the ground of race, color, or national origin, be excluded from participation in, be denied the benefits of, or be subject to discrimination under, any program or activity receiving Federal financial assistance (section 601);

(2) Section 504 of the Rehabilitation Act of 1973, as implemented by 45 CFR part 84, which provides that no qualified handicapped person shall, on the basis of handicap, be excluded from participation in, be denied the benefits of, or otherwise be subject to discrimination under any program or activity receiving Federal financial assistance;

(3) The Age Discrimination Act of 1975, as implemented by 45 CFR part 90, which is designed to prohibit discrimination on the basis of age in programs or activities receiving Federal financial assistance. The Age Discrimination Act also permits federally assisted programs and activities, and recipients of Federal funds, to continue to use certain age distinctions, and factors other than age, that meet the requirements of the Age Discrimination Act and 45 CFR part 90; and

(4) Other pertinent requirements of the Office of Civil Rights of HHS.

(c) In order for a hospital, SNF, HHA, or hospice to be accepted, it must also meet the advance directives requirements specified in subpart I of this part.

(d) The State survey agency will ascertain whether the provider meets the conditions of participation or requirements (for SNFs) and make its recommendations to HCFA.

(Catalog of Federal Domestic Assistance Program No. 93.773, Medicare—Hospital Insurance; and Program No. 93.774, Medicare—Supplementary Medical Insurance Program)

Dated: June 23, 1993.

Bruce C. Vladeck,

Administrator, Health Care, Financing Administration.

Dated: August 9, 1993.

Donna E. Shalala,

Secretary.

[FR Doc. 93–28436 Filed 11–22–93; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

43–CFR Public Land Order #7011

[WY–930–4210–06; WYW–83357]

Partial Revocation of Secretarial Order Dated April 20, 1921; Wyoming

AGENCY: Bureau of Land Management, Interior.

ACTION: Public Land Order.

SUMMARY: This order revokes a Secretarial order insofar as it affects 160 acres of National Forest system land withdrawn for Stock Driveway No. 144, Wyoming No. 18. The land is no longer needed for this purpose, and the revocation is needed to permit disposal of the land through land exchange under the General Exchange Act of 1922. This action will open the land to such forms of disposition as may by law be made of National Forest System land. The land is temporarily closed to mining by a Forest Service exchange proposal.The land has been and will remain open to mineral leasing.

EFFECTIVE DATE: December 23, 1993.

FOR FURTHER INFORMATION CONTACT: Duane Feick, BLM Wyoming State Office, P.O. Box 1828, Cheyenne, Wyoming 82003, 307–775–6127.

By virtue of the authority vested in the Secretary of the Interior by Section 204 of the Federal Land Policy and Management Act of 1976, 43 U.S.C. 1714 (1988), it is ordered as follows:

1. Secretarial Order dated April 20, 1921, which withdrew National Forest System land for Stock Driveway No. 144, Wyoming No. 18, is hereby revoked insofar as it affects the following described land:

Sixth Principal Meridian

Medicine Bow National Forest

T. 30 N., R. 77 W.,
Sec. 32, SE¼SE¼;
Sec. 33, S½SW¼ and SW¼SE¼.

The area described contains 160 acres in Converse and Natrona Counties.

2. At 9 a.m. on December 23, 1993, the land shall be opened to such forms of disposition as may by law be made of National Forest System land, subject to valid existing rights, the provisions of existing withdrawals, other segregations of record, and the requirements of applicable law.

Dated: November 12, 1993.

Bob Armstrong,

Assistant Secretary of the Interior.

[FR Doc. 93–28640 Filed 11–22–93; 8:45 am]

BILLING CODE 4310–22–M

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 90

[PR Docket No. 93–60; FCC 93–450]

Private Land Mobile Radio Services; Co-Channel Protection Criteria Above 800 MHz

AGENCY: Federal Communications Commission.

ACTION: Final rule; correction.

SUMMARY: This document contains a correction to the final regulations [PR Docket No. 93–60, FCC 93–450] which were published Friday, October 15, 1993, (58 FR 53431). The regulations related to certain co-channel protection criteria for private land mobile radio stations operating in the 800/900 MHz bands.

EFFECTIVE DATE: November 15, 1993.

FOR FURTHER INFORMATION CONTACT: Eugene Thomson, Rules Branch, Land Mobile and Microwave Division, Private Radio Bureau, (202) 634–2443.

SUPPLEMENTARY INFORMATION:

Background

The final regulations that are subject to this correction concern co-channel

protection criteria for private land mobile radio systems operating in the 800 MHz and 900 MHz frequency bands and specify procedures to be followed by persons applying for such frequencies pursuant to 47 CFR part 90.

Need for Correction

As published, the final regulations did not include a revision to § 90.615(b)(2)(ii) to change the cross reference to § 90.621(c). Because the final regulations amended § 90.621(c), the reference in § 90.615(b)(2)(ii) to § 90.621(c) is no longer applicable and requires correction.

Correction of Publication

Accordingly, the publication on October 15, 1993 of the final regulations [PR Docket No. 93–60, FCC 93–450] which were the subject of FR Doc. 93–25261, is corrected as follows:

On page 53433, in the first column below the Table, add paragraph 3 at the end of the amendatory text, to read as follows:

3. Section 90.615 is amended by revising paragraph (b)(2)(ii) to read as follows:

§ 90.615 Frequencies available in the General Category.

* * * * *

(b) * * *

(2) * * *

(ii) Each application must include a written signed statement from each co-channel licensee located within 113 km (70 mi) of the primary site of the trunked system verifying that each such licensee has agreed to the proposed trunked use (see exceptions at § 90.621(b)). The statement(s) must include each licensee's call sign.

* * * * *

Federal Communications Commission.

William F. Caton,

Acting Secretary.

[FR Doc. 93–28645 Filed 11–22–93; 8:45 am]

BILLING CODE 6712–01–M

OFFICE OF MANAGEMENT AND BUDGET

Office of Federal Procurement Policy

48 CFR Part 9903

Cost Accounting Standards Board; Applicability and Thresholds for Cost Accounting Standards Coverage

AGENCY: Cost Accounting Standards Board, Office of Federal Procurement Policy, OMB.

ACTION: Correction to final rule.

SUMMARY: This document contains a correction to the final rule revising applicability, thresholds and procedures for the application of Cost Accounting Standards to negotiated government contracts, which was published Thursday, November 4, 1993 (58 FR 58798).

EFFECTIVE DATE: November 4, 1993.

FOR FURTHER INFORMATION CONTACT: Richard C. Loeb, Executive Secretary, Cost Accounting Standards Board (telephone: 202–395–3254).

The final rule published Thursday, November 4, 1993, at 58 FR 58798 is corrected as follows.

§ 9903.201–3 [Corrected]

Instruction paragraph 4. for § 9903.201–3 which begins on page 58801, at the bottom of the third column, and continues at the top of page 58802 in the first column, is corrected on page 58802 by adding the following instruction in the third line after the first semicolon:

4. * * * by removing the amount "$10 million" in the "Caution" statement at the end of paragraph (c)(4) in Part I of the clause and adding the amount "$25 million" in its place; * * *

Dated: November 17, 1993.

[FR Doc. 93–28677 Filed 11–22–93; 8:45 am]

BILLING CODE 3110–01–M

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 625

[Docket No. 930615–3215; I.D. 110793A]

Summer Flounder Fishery

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic Atmospheric Administration (NOAA), Commerce.

ACTION: Notification of commercial quota transfer.

SUMMARY: NMFS issues this notification to announce that 7,815 pounds (3,545 kg) of summer flounder commercial quota available to the State of North Carolina has been transferred to the State of New Jersey. The summer flounder allocated to New Jersey by this transfer can only be harvested under the conditions of a net-mesh selectivity study authorized by the Regional Director. This notification advises the public that the quota adjustment has been made and that the adjusted commercial quota for the State of North Carolina is 3,256,750 pounds (1,477,252 million kg), and the State of New Jersey is 2,073,354 pounds (940,467 million kg).

DATES: Effective November 18, 1993 through December 31, 1993.

ADDRESSES: Comments or questions regarding the experimental fishery for summer flounder should be sent to Richard B. Roe, Regional Director, One Blackburn Drive, Gloucester, MA 01930.

FOR FURTHER INFORMATION CONTACT: Hannah Goodale, Fishery Policy Analyst, 508–281–9101.

SUPPLEMENTARY INFORMATION: Regulations governing the summer flounder fishery are found at 50 CFR part 625 (December 4, 1992, 57 FR 57358). The regulations require the annual specification of a commercial quota that is apportioned among the coastal states from North Carolina through Maine. The process to set the annual commercial quota and the percent allocated to each state are described in § 625.20.

The commercial quota for summer flounder for the 1993 calendar year was set equal to 12.35 million pounds (5.6 million kg) (January 22, 1993, 58 FR 5658). The percent allocated to each state was adjusted by Amendment 4 to the Fishery Management Plan for the Summer Flounder Fishery (September 24, 1993, 58 FR 49937) with 16.72499 percent, or 2,065,539 pounds (936,922 million kg) allocated to New Jersey, and 27.44584 percent, or 3,389,565 pounds (1,537,497 kg) allocated to North Carolina.

An emergency interim rule published August 26, 1993, (58 FR 45075) allows two or more states, under mutual agreement and with the concurrence of the Regional Director, to transfer or combine summer flounder commercial quota. The Regional Director is required to consider the criteria set forth in § 625.20(f)(1) to evaluate requests for quota transfers or combinations.

Further, the Regional Director is required to publish a notification in the **Federal Register** advising a state and notifying Federal vessel and dealer permit holders that, effective upon a specific date, a portion of a state's commercial quota has been transferred to or combined with the commercial quota of another state.

On November 8, 1993, a notification was published announcing a transfer of 125,000 pounds (56,700 kg) of summer flounder commercial quota from the State of North Carolina to the Commonwealth of Virginia (58 FR 59196). The quota for the State of North Carolina was thus reduced to 3,264,565 pounds (1,480,797 kg).

North Carolina and New Jersey have agreed to transfer 7,815 pounds (3,545 kg) of North Carolina's commercial quota to New Jersey. The Regional Director has determined that the criteria set forth in § 625.20 have been met, and publishes this notification of quota transfer. The net-mesh selectivity study is a continuation of an experimental fishery for summer flounder authorized by the Regional Director earlier this year. Details of the design of the experimental fishery are available from the Regional Director (see **ADDRESSES**). The revised quotas for the calendar year 1993 are: North Carolina—3,256,750 pounds (1,477,252 million kg), New Jersey—2,073,354 pounds (940,467 million kg).

Classification

This action is authorized by 50 CFR part 625.

Authority: 16 U.S.C. 1801 *et seq.*

List of Subjects in 50 CFR Part 625

Fisheries, Reporting and recordkeeping requirements.

Dated: November 18, 1993.

Joe P. Clem,

Acting Director of Office Fisheries Conservation and Management, National Marine Fisheries Service.

[FR Doc. 93–28694 Filed 11–18–93; 11:21 am]

BILLING CODE 3510–22–M

50 CFR Part 640

[Docket No. 931102–3302; ID 102793]

Spiny Lobster Fishery of the Gulf of Mexico and South Atlantic

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Final rule, technical amendment.

SUMMARY: NMFS issues this technical amendment to correct a reference in the prohibitions section of the regulations that govern conservation and management of spiny lobster and slipper lobster in the exclusive economic zone off the Atlantic and Gulf of Mexico states from the Virginia/North Carolina border to the U.S./Mexico border. The intended effect of this rule is to correct the regulations.

EFFECTIVE DATE: November 23, 1993.

FOR FURTHER INFORMATION CONTACT: W. Perry Allen, 813–893–3722.

SUPPLEMENTARY INFORMATION: The spiny lobster fishery of the Gulf of Mexico and South Atlantic is managed under the Fishery Management Plan for the Spiny Lobster Fishery of the Gulf of Mexico and South Atlantic (FMP). The FMP was prepared by the Gulf of Mexico and South Atlantic Fishery Management Councils and is implemented through regulations at 50 CFR part 640 under the authority of the Magnuson Fishery Conservation and Management Act.

The regulations at 50 CFR 640.7(n) contain an incorrect reference for the prohibition on pulling or tending a spiny lobster trap other than during daylight hours. This final rule, technical amendment, corrects that reference.

Classification

This technical amendment is issued as a final rule under 50 CFR part 640.

This rule is minor and technical and does not change regulatory impacts that were previously reviewed and analyzed.

Because this rule (1) makes a non-substantive correction to the regulations and (2) will not necessitate a change in operating practices in the spiny lobster fishery, the Assistant Administrator for Fisheries, NOAA, under section 553 (b)(B) and (d) of the Administrative Procedure Act (5 U.S.C. 553) for good cause finds that it is unnecessary and contrary to the public interest to provide notice and public comment on this rule or to delay for 30 days its effective date.

List of Subjects in 50 CFR Part 640

Fisheries, Fishing, Reporting and recordkeeping requirements.

Rolland A. Schmitten,

Assistant Administrator for Fisheries, National Marine Fisheries Service.

For the reasons set forth in the preamble, 50 CFR part 640 is amended as follows:

PART 640—SPINY LOBSTER FISHERY OF THE GULF OF MEXICO AND SOUTH ATLANTIC

1. The authority citation for part 640 continues to read as follows:

Authority: 16 U.S.C. 1801 *et seq.*

§ 640.7 [Revised]

2. In § 640.7, in paragraph (n), the reference to "§ 640.21(b)(2)" is revised to read "§ 640.22(b)(2)".

[FR Doc. 93–28759 Filed 11–22–93; 8:45 am]

BILLING CODE 3510–22–M

Proposed Rules

Federal Register
Vol. 58, No. 224
Tuesday, November 23, 1993

This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

DEPARTMENT OF JUSTICE

Immigration and Naturalization Service

8 CFR Parts 210, 245a, and 274a

[INS No. 1399–92]

RIN 1115–AB73

Control of Employment of Aliens

AGENCY: Immigration and Naturalization Service, Justice.

ACTION: Proposed rule.

SUMMARY: This is a proposed rule to reduce the number of INS-issued documents that are acceptable for purposes of completing the Employment Eligibility Verification Form (Form I–9). This rule is proposed to further simplify compliance with the employment eligibility verification requirements and to address the concerns of employers who allege confusion created by the number of acceptable documents on the Form I–9. Reduction in the number of acceptable documents should reduce any uncertainty on the part of employers, and thereby reduce potential employment discrimination based upon misapplication of the employment eligibility verification requirements.

DATES: Written comments must be submitted on or before December 23, 1993.

ADDRESSES: Please submit written comments, in triplicate, to the Director, Policy Directives and Instructions Branch, Immigration and Naturalization Service, 425 I Street NW., room 5307, Washington, DC 20536. To ensure proper handling, please reference INS number 1399–92 on your correspondence.

FOR FURTHER INFORMATION CONTACT: Michael C. McGoings, Associate General Counsel, Immigration and Naturalization Service, 425 I St. NW., room 6100, Washington, DC 20536, telephone (202) 514–2895.

SUPPLEMENTARY INFORMATION:

Statutory and Regulatory Authority

Part 274a, originally published as a final rule in the **Federal Register** on May 1, 1987, 52 FR 16216, was necessitated by section 101 of the Immigration Reform and Control Act of 1986, Public Law No. 99–603, 100 Stat. 3359 (1986) (IRCA). Section 101 of IRCA added to the Immigration and Nationality Act (Act) provisions relating to the control of employment of aliens in the United States, generally referred to as employer sanctions. Since implementation of these provisions on June 1, 1987, the Immigration and Naturalization Service (INS or Service) has reviewed numerous public comments, reports, and proposals recommending improvements to the employer sanctions procedures. The regulations have been revised on several occasions since 1987. See, *e.g.*, 56 FR 41767 (Aug. 23, 1991).

The Employment Eligibility Verification Form (Form I–9) is the linchpin of the employment eligibility verification system set forth at section 274A(b) of the Act. That section provides that the employer must verify, for every employee hired after November 6, 1986, that the person is not an unauthorized alien. There are three categories of documents that are acceptable for Form I–9 purposes. The first category is referred to as "List A" documents. List A documents establish both a person's identity and eligibility to be employed. Currently, 8 CFR 274a.2(b)(1)(v)(A) identifies the ten (10) types of acceptable List A documents. The second category of documents is referred to as "List B" documents, which establish only identity. There are currently twelve (12) types of acceptable List B documents and they are listed in 8 CFR 274a.2(b)(1)(v)(B). Finally, the third category of documents listed in 8 CFR 274a.2(b)(1)(v)(C) is referred to as "List C" documents, which establish only employment eligibility. There are seven (7) types of acceptable List C documents. Thus, there are a total of twenty-nine (29) types of documents that are acceptable for Form I–9 purposes.

Background

One often repeated criticism of employer sanctions relates to the number of documents that are acceptable for completing the Form I–9. The General Accounting Office (GAO) stated, in its March 1988 report, that the number of acceptable work eligibility documents made it difficult for employers to judge their genuineness. Immigration Control: A New Role for the Social Security Card, (GAO/HRD–88–4, Mar. 1988). In a March 1990 report to Congress on the implementation of employer sanctions, the GAO again noted that "IRCA allows persons to use any of 17 different documents to establish work eligibility [10 types of List A documents and 7 types of List C documents]. This multiplicity can give rise to confusion and uncertainty in the minds of employers seeking to confirm whether job applicants are eligible to work." Immigration Reform: Employer Sanctions and the Question of Discrimination 62 (GAO/GGD–90–62, Mar. 1990). This theme was echoed by the Task Force on IRCA-Related Discrimination, chaired by Assistant Attorney General John R. Dunne. The Task Force's report stated "that a work verification process that relies on fewer documents, and is easier to understand, will measurably reduce discrimination." Report and Recommendation of the Task Force on IRCA-Related Discrimination, 44 (GPO 276–024, Sept. 1990).

The INS has already taken steps to address this criticism. In July 1988, the INS committed to the establishment of procedures for a uniform employment authorization policy. First, the INS limited the number and type of paper documents on which employment could be authorized. Second, the INS introduced the standardized Employment Authorization Document (Form I–688B) in 1989 and implemented it nationwide by August 1990. This document, known as the EAD, is a laminated plastic card containing a photograph and clearly noting the expiration date of, and any limitations on, an alien's work authorization. Issuance of the EAD has standardized the INS' employment authorization issuance process and permitted more accurate data to be collected and compiled relating to work authorization. Further, the EADs contain security features not found on previous INS-issued employment authorization documents that make them more resistant to tampering and fraud. Nationwide, the EAD is issued at

more than 200 sites. For example, these sites include district offices, suboffices, certain airports and ports of entry, asylum offices, service centers, detention processing centers, and border patrol sector offices. Ultimately, this card will be replaced by an even more secure employment authorization document that is currently under development.

The INS has now moved to reduce to one the types of alien registration receipt cards in circulation that are acceptable as proof of lawful permanent resident status and for Form I–9 purposes. The oldest type of alien registration receipt card, designated as Form I–151, was issued prior to June 1978, and was periodically revised. There were 17 different versions of this card. These cards lack sufficient security features and are prone to tampering and fraud. Consequently, a third GAO report noted that during August and September 1989, INS agents reviewed 110 alien registration receipt cards and found 106 (96 percent) to be counterfeit. Immigration Reform: Employer Sanctions and the Question of Discrimination 66 (GAO/GGD–90–62, Mar. 1990). From March 1977, to August 1, 1989, the INS began issuing improved alien registration receipt cards, designated as Form I–551. Beginning on August 1, 1989, the INS began issuing machine-readable Forms I–551 with expiration dates and enhanced security features. The INS on May 28, 1993, published a proposed rule in the Federal Register at 58 FR 31000, concerning the replacement of the previously issued alien registration documents with the new type which is more resistant to fraud. The final rule, published on September 20, 1993 in the Federal Register at 58 FR 48775, terminates the validity of previous versions of the alien registration card effective September 20, 1994. The final rule makes those previous versions of the alien registration card invalid for Form I–9 employment eligibility verification purposes as of that date.

In addition to the improvements outlined above, the INS has determined that further steps can be taken to streamline the employment eligibility verification system by reducing the number of documents that are acceptable for Form I–9 purposes. What follows is a detailed analysis of the changes suggested in this proposed rule.

Analysis of the Proposed Rule

The INS proposes eliminating certain documents from the Form I–9. Each list of documents on the Form I–9 will be analyzed from the standpoint of the documents that the INS proposes eliminating. Note that although the documents would no longer be acceptable for purposes of completing Forms I–9, with the exception of Forms I–151, they would still be valid for the purpose for which they are issued.

List A

The INS proposes removing the following three (3) documents from List A:

Form I–688A, Employment Authorization Card

This employment authorization document is issued to those aliens who have applied for legalization under section 245A of the Act, or for benefits as a special agricultural worker (SAW) under section 210 of the Act, but who have not yet been approved. Although the Form I–688A serves as only an employment authorization document for legalization applicants, it serves as both an employment authorization document and a travel document for SAW applicants. Aliens possessing these documents will be declining in numbers as their applications for relief are either granted or denied. The INS will make a concerted effort to eliminate the backlog of SAW applications pending with the service centers. However, the INS also recognizes that pending litigation and appeals of denials of SAW status make it likely that some aspects of the SAW program will continue for some time. Therefore, aliens in possession of the Form I–688A will be issued an EAD, Form I–688B, to evidence employment authorization. Special agricultural worker applicants will be granted advanced parole under section 212(d)(5) of the Act, if they wish to travel during the pendency of their SAW application. The regulations at 8 CFR 210.4(b) and 8 CFR 245a.3(n) will be amended to delete the references to Form I–688A and to reflect that the Form I–688B can be obtained at designated INS offices, and not just at legalization offices. In addition, a new paragraph (20) will be added to 8 CFR 274a.12(c) to reflect that aliens who have applied for temporary residence under the legalization or SAW provisions of the Act are authorized for employment.

Form I–327, Re-Entry Permit

Aliens in possession of this document are lawful permanent residents and, as such, are in possession of alien registration receipt cards. While no security concerns have been identified with this document, bearers will suffer no hardship by its elimination since they already possess an acceptable alternative document for Form I–9 purposes.

Form I–571, Refugee Travel Document

This document is issued only to aliens who have been admitted as refugees under section 207 of the Act, have been granted asylum status in the United States under section 208 of the Act, or who are lawfully admitted for permanent residence. These individuals may obtain an EAD, Form I–688B, in accordance with 8 CFR 274a.12 (a)(3) or (a)(5), or, when statutorily eligible, they may adjust their status to lawful permanent resident aliens, thereby becoming entitled to an alien registration receipt card, Form I–551, in accordance with 8 CFR 274a.12(a)(1).

List B

The INS proposes combining two (2) document categories and removing the following five (5) documents from List B:

Proposed Combined Documents

Driver's Licenses and Identification Cards

Certain redundancy is present in two categories in List B. 8 CFR 274a.2(b)(1)(v)(B)(1)(i) states that certain driver's licenses and identification cards are acceptable evidence of identity. 8 CFR 274a.2(b)(1)(v)(B)(1)(v) also permits certain identification documents to be used as acceptable evidence of identity. The INS proposes combining these two categories. The INS has received numerous inquiries concerning local documents such as fishing licenses, which arguably contain sufficient identifying information to satisfy the regulatory definition. However, these documents are issued through a process that does not preserve the document's security. All states now issue identification cards, thereby permitting the elimination of local identification documents.

Proposed Eliminated Documents

School Identification Cards

The myriad of school identification documents adds unnecessary complexity and confusion to the employment eligibility verification system. Students may obtain either a state driver's license or identification card, or, if they are under the age of 18, their parents or legal guardians may attest to their identity in accordance with 8 CFR 274a.2(b)(1)(v)(B)(3).

Voter's Registration Cards

On June 25, 1990, the INS published an interim rule in the Federal Register at 56 FR 25928, removing this document as an acceptable identity document for Form I–9 purposes because it lacks the proper indicia of identity, such as a

photograph or other personal identifying information, that would qualify it as an acceptable List B document. However, based on a comment submitted that indicate that some individuals' sole identity document is their voter's registration card, the voter's registration cards was reinstated, as an acceptable List B document, in the final rule published on August 23, 1991, at 56 FR 41767.

The problem of document fraud and the need to simplify the Form I–9 process now mandate that the voter's registration card be removed from List B. The INS has continued to doubt the acceptability of a voter's registration card to establish identity. Most contain very little identifying information, and the issuance process is quite insecure. In addition, some local governments now allow non-citizens to vote in local elections. See Los Angeles Times, November 13, 1991, at B7, col. 1 (reporting that in Takoma Park, Maryland, voters approved a measure to extend the right to vote in municipal elections to residents who are not United States citizens; noting that Somerset, Maryland, has permitted non-citizen voting in local elections for decades; and further reporting that in New York and Chicago, parents of children in public schools may vote in school board elections regardless of citizenship). Persons in possession of voter's registration cards should be able to obtain appropriate alternative documents to comply with the requirements of the employment eligibility verification system. Moreover, the group referred to in the regulation was restricted to a small group of employees in one particular company.

U.S. Military Documents

The necessity to streamline the employment eligibility verification system has caused the INS to propose eliminating documents that are not capable of specific definition and whose bearers could readily obtain alternative documents. Military identification fits both criteria. The INS has never specifically defined what was included within this regulatory provision because the types of military identification are too numerous. In addition, members of the armed services should already possess or readily be able to obtain other documents that remain acceptable for completion of Forms I–9.

U.S. Coast Guard Merchant Mariner Cards

This document is issued only to United States citizens and aliens lawfully admitted for permanent residence. Citizen merchant mariners can obtain a social security card combined with an identity document, or a U.S. passport. Lawful permanent resident alien merchant mariners should already possess a Form I–551.

Documents for Individuals Under the Age of 18

The current regulations at 8 CFR 274a.2(b)(1)(v)(B)(*2*) permit three (3) additional types of documents to be used by minors under the age of 18 to establish identity. These are: school records or report cards; clinic, doctor, or hospital records; and day-care or nursery school records. Originally, these documents were included on Form I–9 to address those situations where children are involved in employment situations. However, this class of employee is quite small in relation to the total number of persons hired for employment in the United States each year. In addition, a perfectly acceptable alternative exists for these minors. Under 8 CFR 274a.2(b)(1)(v)(B)(*3*), minors under the age of 18 are exempt from producing an identity document if their parent or legal guardian attests on the Form I–9. Therefore, these minors are capable of satisfying the employment eligibility verification requirements without having to produce any identity document.

List C

The INS proposes modifying the regulatory language relating to one (1) document and removing the following three (3) documents from List C:

Forms FS–545 and DS–1350, Certificates of Birth Abroad

United States citizens born abroad would be able to obtain other documents that U.S. citizens may obtain, such as the combination of an identity document and a social security card, or a U.S. passport.

Form I–197, U.S. Citizen I.D. Card

This card has not been issued since the early 1980's. Persons in possession of this document would be able to obtain other documents that United States citizens may obtain, such as the combination of an identity document and a social security card, or a U.S. passport.

Form I–179, I.D. Card For Use of Resident Citizen in the United States

This document has not been issued since the 1970's. Persons in possession of this document would be able to obtain other documents that U.S. citizens may obtain, such as the combination of an identity document and a social security card, or a U.S. passport.

In accordance with 5 U.S.C. 605(b), the Commissioner of the Immigration and Naturalization Service certifies that this rule does not have a significant adverse economic impact on a substantial number of small entities. This rule is not considered to be a major rule within the meaning of section 1(b) of E.O. 12291, nor does this rule have Federalism implications warranting the preparation of a Federalism Assessment in accordance with E.O. 12612.

The information collection requirements contained in this rule have been cleared by the Office of Management and Budget under the provisions of the Paperwork Reduction Act. Clearance numbers for these collections are contained in 8 CFR 299.5, Display of Control Numbers.

List of Subjects

8 CFR Part 210

Aliens, Migrant labor, Reporting and recordkeeping requirements.

8 CFR Part 245a

Aliens, Immigration, Reporting and recordkeeping requirements.

8 CFR Part 274a

Administrative practice and procedure, Aliens, Employment, Penalties, Reporting and recordkeeping requirements.

Accordingly, chapter I of title 8 of the Code of Federal Regulations is proposed to be amended as follows:

PART 210—SPECIAL AGRICULTURAL WORKERS

1. The authority citation for part 210 is revised to read as follows:

Authority: 8 U.S.C. 1103, 1160, 8 CFR part 2.

2. In § 210.4, paragraphs (b) (2) and (3) would be revised to read as follows:

§ 210.4 Status and benefits.

* * * * *

(b) * * *

(2) *Employment and travel authorization prior to the granting of temporary resident status.* Permission to travel abroad and to accept employment will be granted to the applicant after an interview has been conducted in connection with a nonfrivolous application at a Service office. If an interview appointment cannot be scheduled within 30 days from the date an application is filed at a Service office, authorization to accept employment will be granted, valid until the scheduled appointment date. Employment authorization, both prior

and subsequent to an interview, will be granted on Form I–688B, and will be restricted to six months duration, pending final determination on the application for temporary resident status. If a final determination has not been made on the application prior to the expiration date of the I–688B, that date may be extended upon return of the I–688B by the applicant to the Service office where it was obtained. Persons submitting applications who currently have work authorization incident to status as defined in § 274a.12(b) of this chapter shall be granted work authorization by the INS effective on the date the alien's prior work authorization expires. Permission to travel abroad shall be granted in accordance with the Service's advance parole provisions contained in § 212.5(e) of this chapter.

(3) *Employment and travel authorization upon grant of temporary resident status.* Upon the granting of an application for adjustment to temporary resident status, the service center will forward a notice of approval to the applicant at his or her last known address and to his or her qualified designated entity or representative. The applicant may appear at any Service office, and upon surrender of the previously issued Form I–688B, will be issued Form I–688, Temporary Resident Card. An alien whose status is adjusted to that of a lawful temporary resident under section 210 of the Act has the right to reside in the United States, to travel abroad (including commuting from a residence abroad), and to accept employment in the United States in the same manner as aliens lawfully admitted for permanent residence.

* * * * *

PART 245a—ADJUSTMENT OF STATUS TO THAT OF PERSONS ADMITTED FOR LAWFUL TEMPORARY OR PERMANENT RESIDENT STATUS UNDER SECTION 245A OF THE IMMIGRATION AND NATIONALITY ACT, AS AMENDED BY PUB. L. 99–603, THE IMMIGRATION REFORM AND CONTROL ACT OF 1986, AND PUB. L. 100–204, SECTION 902

3. The authority citation for part 245a continues to read as follows:

Authority: 8 U.S.C. 1101, 1103, 1255a and 1255a note.

4. In § 245a.2, paragraphs (n) (2) (ii) and (3) would be revised to read as follows:

§ 245a.2 Application for temporary residence.

* * * * *

(n) * * *

(2) *Employment authorization prior to the granting of temporary resident status.*

(i) * * *

(ii) If an interview appointment cannot be scheduled within 30 days from the date an application is filed at a Service office, authorization to accept employment will be granted valid until the scheduled appointment date. Employment authorization, both prior and subsequent to an interview, will be granted on Form I–688B, and will be restricted to six months duration, pending final determination on the application for temporary resident status.

(3) *Employment and travel authorization upon grant of temporary resident status.* Upon the granting of an application for adjustment to temporary resident status, the service center will forward a notice of approval to the applicant at his or her last known address and to his or her qualified designated entity or representative. The applicant may appear at any Service office, and upon surrender of the previously issued Form I–688B will be issued Form I–688, Temporary Resident Card.

* * * * *

PART 274a—CONTROL OF EMPLOYMENT OF ALIENS

5. The authority citation for part 274a continues to read as follows:

Authority: 8 U.S.C. 1101, 1103, 1324a, and 8 CFR part 2.

6. Section 274a.2(b)(1)(v) would be amended by:

a. removing paragraphs (A)(*4*)(*i*) and (A)(*5*);

b. revising paragraphs (A)(*6*), (A)(*7*), (A)(*8*), and (A)(*9*);

c. revising paragraph (A)(*10*) and redesignating it as paragraph (A)(*6*);

d. revising paragraph (B) introductory text and paragraphs (B)(*1*) and (B)(*1*)(*i*);

e. removing paragraphs (B)(*1*)(*ii*), (B)(*1*)(*iii*), (B)(*1*)(*iv*), (B)(*1*)(*v*), (B)(*1*)(*vi*) and (B)(*1*)(*viii*);

f. revising paragraphs (B)(*1*)(*vii*) and redesignating it as paragraph (B)(*1*)(*ii*);

g. revising paragraphs (B)(*1*)(*ix*) and redesignating it as paragraph (B)(*1*)(*iii*);

h. removing paragraph (B)(*2*);

i. redesignating paragraphs (B)(*3*) and (B)(*4*) as paragraphs (B)(*2*) and (B)(*3*) respectively;

j. revising paragraphs (C)(*1*);

k. removing paragraphs (C)(*2*), (C)(*3*), (C)(*6*) and (C)(*7*);

l. revising paragraphs (C)(*4*), (C)(*5*) and (C)(*8*) and redesignating them as paragraphs (C)(*2*), (C)(*3*) and (C)(*4*) respectively to read as follows:

§ 274a.2 Verification of employment eligibility.

* * * * *

(b) * * *

(1) * * *

(v) * * *

(A) * * *

(*4*) * * *

(*i*) Contains an unexpired stamp therein which reads, "Processed for I–551. Temporary Evidence of Lawful Admission for permanent residence. Valid until _____. Employment authorized" or "Temporary Form I–551. Admission for permanent residence at _____ (port)_____ (date) verified. _____ (office of issuance)_____ (date) _____ (signature of issuing officer) _____ (title)"; either stamp may be placed on the arrival portion of Form I–94, with the alien's picture affixed thereto, if the alien is not in possession of his or her passport; or

* * * * *

(*5*) An Alien Registration Receipt Card, INS Form I–551; or

(*6*) An unexpired employment authorization document issued by the Immigration and Naturalization Service which contains a photograph, INS Form I–688, or I–688B.

(B) The following documents and procedures are acceptable to establish identity only:

(*1*) The following documents, whether expired or unexpired are acceptable to establish identity only:

(*i*) A driver's license or identification card issued by the Federal Government, a state (as defined in section 101(a)(36) of the Act), or an outlying possession (as defined in section 101(a)(29) of the Act) of the United States, provided the document contains a photograph or the following information: name, date of birth, sex, height, eye color, and address;

(*ii*) A Native American tribal document; or

(*iii*) A driver's license issued by a Canadian Government authority, or a Canadian federal or provincial identification card.

* * * * *

(C) * * *

(*1*) A social security card with no employment restrictions;

(*2*) An original or certified copy of a birth certificate issued by a state (as defined in section 101(a)(36) of the Act), county, municipal authority, or outlying possession of the United States (as defined in section 101(a)(29) of the Act) bearing an official seal;

(*3*) A Native American tribal document; or

(*4*) An unexpired Form I–94 indicating admission as refugee or

containing an employment authorization stamp, so long as the period of endorsement has not yet expired and the proposed employment is not in conflict with any restrictions or limitations identified thereon.

* * * * *

7. Section 274a.12(c) would be amended by removing the "." at the end of paragraph (19) and replacing it with a ";" and adding a new paragraph (20) to read as follows:

§ 274a.12 Classes of aliens authorized to accept employment.

* * * * *

(c) * * *

(20) An alien who has filed an application for lawful temporary residence pursuant to section 245A or 210 of the Act. Such an alien shall apply for employment authorization only in accordance with the procedures set forth in parts 245a or 210 of this chapter.

Dated: November 16, 1993.

Doris Meissner,

Commissioner, Immigration and Naturalization Service.

[FR Doc. 93-28676 Filed 11-22-93; 8:45 am]

BILLING CODE 4410-10-M

DEPARTMENT OF THE TREASURY

Office of Thrift Supervision

12 CFR Part 574

[No. 93-60]

RIN 1550-AA63

Acquisition of Control of Savings Associations Applications, Approval Standards and Procedural Requirements

AGENCY: Office of Thrift Supervision, Treasury.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Office of Thrift Supervision (OTS) proposes to amend its acquisition of control regulations to incorporate the provisions of section 211 of the Federal Deposit Insurance Corporation Improvement Act of 1991 (FDICIA). Section 211, which became effective upon the enactment of the FDICIA on December 19, 1991, amended Section 10(e) of the Home Owners' Loan Act (HOLA) to require that the OTS, in reviewing a holding company application under section 10(e) to acquire a savings association, consider the competence, experience, and integrity of the officers, directors, and principal shareholders of the proposed acquirors and the savings association to be acquired.

Section 211 also amended section 10(e) of the HOLA to set forth two additional circumstances under which the Director is required to deny a holding company application. First, the OTS must deny an application under section 10(e) of the HOLA if the company fails to provide adequate assurances to the OTS that the company will make available to the OTS such information on the operations or activities of the company, and any affiliate of the company, as the OTS determines to be appropriate to determine and enforce compliance with the HOLA. Second, the statute requires the OTS to deny an application by a foreign bank if the foreign bank is not subject to comprehensive supervision or regulation on a consolidated basis by the appropriate authorities in the home country of the foreign bank.

In addition, the OTS proposes to amend its acquisition of control regulations to reflect the previous combination of the various holding company application forms in order to provide consistency between the forms and the regulations, to eliminate confusion, and to streamline the regulations.

DATES: Comments must be received on or before December 23, 1993.

ADDRESSES: Send comments to Director, Information Services Division, Public Affairs, Office of Thrift Supervision, 1700 G Street, NW., Washington, DC 20552, Attention Docket No. 92-60. These submissions may be hand delivered to 1700 G Street, NW. from 9 a.m. to 5 p.m. on business days; they may be sent by facsimile transmission to FAX Number (202) 906-7753 or (202) 906-7755. Submissions must be received by 5 p.m. on the day they are due in order to be considered by the OTS. Late-filed, misaddressed or misidentified submissions will not be considered in this rulemaking. Comments will be available for inspection at 1700 G Street, NW. from 1 to 4 p.m. on business days. Visitors will be escorted to and from the Public Reference Room at established intervals.

FOR FURTHER INFORMATION CONTACT: David Sjogren, Program Manager, Corporate Analysis, (202) 906-6739, Supervisory Operations, Eileen McCarthy, Program Analyst, Thrift Policy, (202) 906-5752, Supervision Policy, Kevin A. Corcoran, Assistant Chief Counsel, (202) 906-6962, or V. Gerard Comizio, Deputy Chief Counsel, (202) 906-6411, Corporate and Securities Division, Office of Thrift Supervision, 1700 G Street, NW., Washington, DC 20552.

SUPPLEMENTARY INFORMATION:

I. Acquisition Standards

Section 10(e) of the HOLA, 12 U.S.C. 1467a, generally prohibits any company, directly or indirectly, from acquiring control of a savings association without prior OTS approval. The OTS is required to evaluate holding company applications under the standards set forth at section 10(e) of the HOLA. In reviewing any holding company acquisition under section 10(e), the OTS is required to take into consideration the financial and managerial resources and future prospects of the company and association involved, the insurance risk to the SAIF or the BIF, and the convenience and needs of the community to be served.[1]

A. Competence, Experience, and Integrity of Officers, Directors, and Principal Shareholders

Section 211 of the FDICIA, Public Law No. 102-242, 105 stat. 2236, amended sections 10(e)(1)(B) and 10(e)(2) of the HOLA to require that the OTS, in considering the managerial resources of companies and savings associations involved in a holding company acquisition, consider "the competence, experience, and integrity of the officers, directors, and principal shareholders of the company or association."[2]

Neither the HOLA nor the OTS acquisition of control regulations defines the term "principal shareholder." The OTS acquisition of control regulations, however, define the term "controlling shareholder" as "any person who directly or indirectly or acting in concert with one or more persons or companies, or together with members of his or her immediate family, owns, controls, or holds with power to vote 10 percent or more of the voting stock of a company or controls in any manner the election or appointment of a majority of the company's board of directors."[3]

The OTS believes that the definition of the term "controlling shareholder" currently contained in its acquisition of

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[1] 12 U.S.C. 1467a(e)(1)(B) and (e)(2). These standards also apply to acquisitions of stock in connection with qualified stock issuances under section 10(q) of the HOLA, and any transaction under section 13(k) of the Federal Deposit Insurance Act.

[2] *Id.* In assessing the managerial resources of proposed acquirors of savings associations, the OTS has, as a matter of practice and policy, generally interpreted this standard to require a review of the competence, experience, and integrity of proposed acquirors. Thus, the OTS believes that the new statutory requirements of section 10(e)(1)(B) and (2) are consistent with, and enhance, approval standards currently used by OTS.

[3] 12 CFR 574.2(g).

control regulations encompasses the shareholders intended to be treated as "principal shareholders." Accordingly, the proposed amendments, rather than including a separate definition of "principal shareholders," rely on the existing OTS terminology "controlling shareholder" and require the OTS to consider the competence, experience, and integrity of "controlling shareholders."[4]

The statutory language, however, does not prevent the OTS from considering the extent to which a "principal shareholder" or "controlling shareholder" is involved in the affairs of a savings association or savings and loan holding company. An underlying purpose of section 211 is to permit the OTS to consider the abilities of the principal shareholders of savings associations and savings and loan holding companies in appropriate situations, including situations where a principal shareholder has or could have a significant effect on the financial and managerial resources, future prospects, or safety and soundness of a savings association or savings and loan holding company. Thus, the OTS, in weighing the shareholder's experience and competence, would give significant consideration to whether the shareholder proposes to be a passive investor. For instance, a principal shareholder who holds a passive investment would not need the same level of experience and competence required of a principal shareholder who could exert significant influence upon the direction of the savings association or savings and loan holding company.

B. Assurances Regarding Availability of Information

Section 211 of FDICIA added new section 10(e)(2)(C) to the HOLA, which provides that the OTS shall not approve a holding company application if the company fails to provide adequate assurances to the OTS that the company will make available to the OTS such information on the operations or activities of the company, and any affiliate of the company, as the OTS determines to be appropriate to determine and enforce compliance with the HOLA.

This standard applies both to applications submitted by foreign acquirors and domestic acquirors. The assurances apply to affiliates that are under common control of an individual as well as to those under common control of a company.

The OTS specifically requests comment on whether the OTS should, in all instances, seek specific assurances from applicants. The OTS currently seeks all information needed to consider holding company applications,[5] has promulgated regulations and issued forms that require savings and loan holding companies to file information with the OTS on a regular basis,[6] and has broad authority under section 10(b) of the HOLA to examine savings and loan holding companies and their affiliates. In addition, the OTS has broad authority to investigate and bring enforcement actions against holding companies and other affiliates of savings associations under section 10(g) of the HOLA, as well as other statutory provisions, including section 8 of the Federal Deposit Insurance Act.

In processing applications submitted by foreign acquirors, the OTS has, as a matter of policy, required foreign acquirors to enter into a foreign acquiror agreement.[7] Foreign acquiror agreements generally state, *inter alia,* that the foreign acquiror (i) voluntarily consents to United States jurisdiction for purposes of laws relating to United States depository institutions, (ii) shall designate agents for service of process, and (iii) shall permit the OTS to examine it to such extent as the Director may prescribe.

The OTS solicits comment as to whether, for purposes of enforcing United States depository institution laws, this type of agreement is sufficient to ensure personal jurisdiction over all foreign parties that directly or indirectly control savings associations, or are otherwise involved in the affairs of a savings association.

Further, the OTS solicits comment on the precise nature of the assurances that the OTS should consider to be adequate regarding access to information concerning domestic or foreign holding companies or other affiliates, and the manner in which such assurances should be presented to the OTS (*e.g.,* submission of an affidavit, certification, or line item of an application).

C. Comprehensive Supervision and Regulation of Foreign Banks

New section 10(e)(2)(D) of the HOLA, also added by the FDICIA, provides that the OTS shall not approve a holding company application by a foreign bank if the foreign bank is not subject to comprehensive supervision or regulation on a consolidated basis by appropriate authorities in the bank's home country.

The statute, by its terms, relates to foreign banks, and does not address foreign bank holding companies. The OTS specifically requests comment on whether the OTS should include foreign bank holding companies, or subsidiaries of a foreign bank holding company that would not themselves become holding companies, within the scope of the regulation implementing new section 10(e)(2)(D) of the HOLA, thereby requiring that such entities be subject to comprehensive supervision or regulation on a consolidated basis in the appropriate home country.[8]

In processing holding company applications by foreign banks, the OTS will be required to address the question of what constitutes "comprehensive supervision or regulation on a consolidated basis by the appropriate authorities." The OTS specifically requests comment regarding the manner in which the OTS should implement this standard. The OTS could, for example, address this question on a case-by-case basis. In the alternative, the OTS could establish a general definition, or provide other guidance as to the type of supervision that satisfies this standard, and require each foreign bank involved in an acquisition transaction to demonstrate that it is subject to the appropriate level of supervision. Finally, the OTS could take a position on a country-by-country, or regulator-by-regulator basis.

The OTS notes that the Federal Reserve Board, in implementing section 202(a) of the FDICIA, has promulgated a regulation setting forth the basis on which the Federal Reserve Board will determine the presence of "comprehensive supervision or regulation on a consolidated basis."[9] The regulation provides that the Federal Reserve Board will determine whether the foreign bank is supervised or regulated in such a manner that its home country supervisor receives sufficient information on the worldwide

[4] This proposed treatment is consistent with the scope of the "principal shareholder" concept used by the Board of Governors of the Federal Reserve System ("Federal Reserve Board") in implementing section 210 of the FDICIA. See 58 FR 471, 472 (Jan. 6, 1993).

[5] See OTS Form H–(e)__.

[6] See 12 CFR 584.1 and OTS Forms H–(b)10 and H–(b)11.

[7] In addition, the OTS has required parties that attempt to rebut a rebuttable determination of control under 12 CFR 574.4(b) and 574.4(e) to file a foreign holding company agreement.

[8] The Federal Reserve Board, in promulgating final regulations implementing section 202(a) of the FDICIA, has stated that the comprehensive supervision standard is established in the context of supervision of the bank itself. The Federal Reserve Board has stated that the comprehensive supervision standard focuses on, among other things, how the supervisor reviews transactions between a foreign bank and its affiliates, rather than on direct supervision of these companies. See 58 FR 6348, 6349–6350 (January 28, 1993).

[9] See 58 FR 6348, 6360–6361 (to be codified as 12 CFR 211.24(c)(1)(ii)).

operations of the foreign bank (including the relationships of the bank to any affiliate) to assess the foreign bank's overall financial condition and compliance with law and regulation.[10] The Federal Reserve Board has stated that as the standard requires a bank-specific determination, it will address the standard on a case-by-case basis, and not make any blanket pronouncements.[11]

II. Holding Company Application Forms

Previously, potential holding company acquirors of savings associations were required to determine which of five separate holding company application forms, H–(e)1, H–(e)2, H–(e)3, H–(e)4, or H–(e)1–S, was required to be filed in connection with an acquisition subject to part 574. These separate forms, each containing different instruction and form requirements, were originally deemed necessary to accommodate different types of holding company acquirors and transactions.

While it has been useful to OTS review of holding company applications to be able to readily identify different types of acquisition transactions, the differing form requirements and related instructions for each application has caused some degree of confusion and resulted in unnecessary complexity in connection with filing these forms. Thus, the OTS decided to merge the five forms into one comprehensive form with uniform instructions and form requirements. This new combined form contains uniform instructions pertaining to all types of holding company transactions. Further, duplicative information requirements contained in the previous forms, and those currently contained in § 574.6(a)(2) relating to H–(e)1–S applications, have been eliminated, as have numerous information items that are no longer relevant. Also, information routinely requested by the staff has been incorporated into the new combined form to reduce the necessity of additional information requests in connection with OTS review of such filings. The surviving form has been designated as the Application/Information Filing H–(e)_____ (OMB no. 1550–0015).[12]

In light of these form changes, the OTS proposes to amend part 574 to reflect the already-completed merger of the various forms in order to provide consistency between the forms and the regulations, to eliminate confusion, and to streamline the regulations.

Request for Public Comment

The OTS requests public comment on all aspects of the proposal.

III. Executive Order 12866

The Director of the OTS has determined that this proposal does not constitute a "significant regulatory action" for purposes of Executive Order 12866.

IV. Regulatory Flexibility Act

It is certified that this proposal will not have a significant economic impact on a substantial number of small entities. Consequently, a Regulatory Flexibility Analysis is not required.

List of Subjects in 12 CFR Part 574

Administrative practice and procedure, Holding companies, Reporting and recordkeeping requirements, Savings associations, Securities.

Accordingly, the Office of Thrift Supervision hereby proposes to amend part 574, subchapter D, chapter V, title 12, Code of Federal Regulations as set forth below:

PART 574—[AMENDED]

1. The authority citation for part 574 is revised to read as follows:

Authority: 12 U.S.C. 1467a, 1817, 18311i.

2. Section 574.6 is amended by revising paragraph (a) to read as follows:

§ 574.6 Procedural requirements.

(a) *Form of application or notice.* An application, notice, or informational filing required by § 574.3 of this part shall be filed on the Application/Information Filing H–(e)_____ form. (As specified in the form's instructions, the blank line following the H–(e) should be filled in by applicants with the appropriate "1", "1–S", "2", "3", or "4" depending on the type of application.) The specific application requirements for each type of filing are indicated on the form. An acquiror may request confidential treatment of portions of an application or notice only by complying with the requirements of paragraph (f) of this section. In the case of an application involving a merger (including a merger with an interim association) the Application/Information Filing H–(e)_____ form shall be used in lieu of an application that otherwise would be required for such merger under §§ 546.2, 552.13, and 563.22 of this chapter.

(1) *H–(e)1.* This application type shall be filed under § 574.3(a) of this part by a company, other than a savings and loan holding company, for approval to acquire direct or indirect control of one savings association.

(2) *H–(e)1–S.* This application type shall be filed under § 574.3(a) of this part by a savings association for approval to reorganize into a holding company structure, provided that the proposed transaction satisfies each of the conditions for automatic approval specified in §§ 574.7 (a)(2) and (a)(3) of this part.

(3) *H–(e)2.* This application type shall be filed under § 574.3(a) of this part:

(A) By a savings and loan holding company for approval to acquire and hold separately one or more savings associations;

(B) By any other company for approval to acquire and hold separately more than one savings association;

(C) By a savings and loan holding company for approval of an acquisition of shares issued by a savings association in a qualified stock issuance pursuant to § 574.8 of this part; or

(D) By any director, officer, or any individual who owns, controls, or holds with power to vote (or holds proxies representing) more than 25 percent of the voting shares of a savings and loan holding company for approval of an acquisition of one or more savings associations.

(ii) The OTS may determine as a general matter or on a case-by-case basis not to require application information not relevant to transactions described in paragraphs (a)(3)(i) (C) and (D) of this section.

* * * * *

3. Section 574.7 is amended by revising the section heading and paragraph (c) to read as follows:

§ 574.7 Determination by the OTS.

* * * * *

[10] *Id.* The regulation sets forth certain factors that the Federal Reserve Board will assess, including the extent to which the home country supervisor: Ensures that the foreign bank has adequate procedures for monitoring and controlling its activities worldwide; obtains information on the foreign bank and its subsidiaries and offices outside the home country through regular reports of examination, audit reports, or otherwise; obtains information on the dealings and relationships between the foreign bank and its foreign and domestic affiliates; receives from the foreign bank financial reports that are consolidated on a worldwide basis, or comparable information; and evaluates prudential standards, such as capital adequacy and risk asset exposure, on a worldwide basis.

[11] The Federal Reserve Board, however, stated that it expects, as it acts on applications, to use information already reviewed regarding comprehensive supervision in particular countries to make judgments without requiring significant input from similar applicants chartered in the same country. See 58 FR 6348, 6349.

[12] As specified in the form's instructions, the blank line following the H–(e) should be filled in by applicants with the appropriate "1", "1–S", "2", "3", or "4" depending on the type of application.

(c) *Application criteria.* (1) The OTS may deny an application by a company or certain persons, described in paragraph (b) of this section, affiliated with a savings and loan holding company, to acquire control of a savings association, or by a savings and loan holding company to acquire a qualified stock issuance pursuant to § 574.8 of this part:

(i) If the OTS finds that the financial and managerial resources and future prospects of the acquiror and association involved would be detrimental to the association or the insurance risk of the SAIF or BIF; or

(ii) If the acquirer fails or refuses to furnish information requested by the OTS.

(2) Consideration of the managerial resources of a company or savings association shall include consideration of the competence, experience, and integrity of the officers, directors, and controlling shareholders of the company or association. In connection with the applications filed pursuant to §§ 574.6 (a)(2) and (a)(3), and 574.8 of this part, the OTS will also consider the convenience and needs of the community to be served. Moreover, the OTS shall not approve any proposed acquisition:

(i) Which would result in a monopoly, or which would be in furtherance of any combination or conspiracy to monopolize or to attempt to monopolize the savings and loan business in any part of the United States;

(ii) The effect of which on any section of the country may be substantially to lessen competition, or tend to create a monopoly, or which in any other manner would be in restraint of trade, unless the OTS finds that the anticompetitive effects of the proposed acquisition are clearly outweighed in the public interest by the probable effect of the acquisition in meeting the convenience and needs of the community to be served;

(iii) If the company fails to provide adequate assurances to the OTS that the company will make available to the OTS such information on the operations or activities of the company, and any affiliate of the company, as the OTS determines to be appropriate to determine and enforce compliance with the Home Owners' Loan Act; or

(iv) In the case of an application by a foreign bank, if the foreign bank is not subject to comprehensive supervision or regulation on a consolidated basis by the appropriate authorities in the home country of the foreign bank.

* * * * *

Dated: April 26, 1993.

By the Office of Thrift Supervision.

Jonathan L. Fiechter,

Acting Director.

Editorial Note: This document was received at the Office of the Federal Register on November 18, 1993.

[FR Doc. 93-28721 Filed 11-22-93; 8:45 am]

BILLING CODE 6720-01-P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. 93-NM-161-AD]

Airworthiness Directives; McDonnell Douglas Model DC-9-80 Series Airplanes and Model MD-88 Airplanes

AGENCY: Federal Aviation Administration, DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: This document proposes the adoption of a new airworthiness directive (AD) that is applicable to certain McDonnell Douglas Model DC-9-80 series airplanes and Model MD-88 airplanes. This proposal would require inspection of the ceiling pressure relief panels in the cargo compartments to determine if slotted attach points are present and, if not, modification of the panels. This proposal is prompted by a report that certain panels were manufactured without the appropriate slotted attach points. The actions specified by the proposed AD are intended to ensure that the action of the cargo compartment pressure relief panels will enable the airplane to withstand a rapid decompression caused by a hole below the compartment floor.

DATES: Comments must be received by January 25, 1994.

ADDRESSES: Submit comments in triplicate to the Federal Aviation Administration (FAA), Transport Airplane Directorate, ANM-103, Attention: Rules Docket No. 93-NM-161-AD, 1601 Lind Avenue, SW., Renton, Washington 98055-4056. Comments may be inspected at this location between 9 a.m. and 3 p.m., Monday through Friday, except Federal holidays.

The service information referenced in the proposed rule may be obtained from McDonnell Douglas Corporation, P. O. Box 1771, Long Beach, California 90846-0001, Attention: Business Unit Manager, Technical Publications, C1-HDR (54-80). This information may be examined at the FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington; or at the Los Angeles Aircraft Certification Office, FAA, Transport Airplane Directorate, 3229 East Spring Street, Long Beach, California.

FOR FURTHER INFORMATION CONTACT: David Hempe, Aerospace Engineer, Airframe Branch, ANM-120L, FAA, Transport Airplane Directorate, Los Angeles Aircraft Certification Office, 3229 East Spring Street, Long Beach, California 90806-2425; telephone (310) 988-5224; fax (310) 988-5210.

SUPPLEMENTARY INFORMATION:

Comments Invited

Interested persons are invited to participate in the making of the proposed rule by submitting such written data, views, or arguments as they may desire. Communications shall identify the Rules Docket number and be submitted in triplicate to the address specified above. All communications received on or before the closing date for comments, specified above, will be considered before taking action on the proposed rule. The proposals contained in this notice may be changed in light of the comments received.

Comments are specifically invited on the overall regulatory, economic, environmental, and energy aspects of the proposed rule. All comments submitted will be available, both before and after the closing date for comments, in the Rules Docket for examination by interested persons. A report summarizing each FAA-public contact concerned with the substance of this proposal will be filed in the Rules Docket.

Commenters wishing the FAA to acknowledge receipt of their comments submitted in response to this notice must submit a self-addressed, stamped postcard on which the following statement is made: "Comments to Docket Number 93-NM-161-AD." The postcard will be date stamped and returned to the commenter.

Availability of NPRMs

Any person may obtain a copy of this NPRM by submitting a request to the FAA, Transport Airplane Directorate, ANM-103, Attention: Rules Docket No. 93-NM-161-AD, 1601 Lind Avenue, SW., Renton, Washington 98055-4056.

Discussion

A production quality check at the manufacturer's facility revealed that certain cargo compartment ceiling pressure relief panels installed on McDonnell Douglas Model DC-9-80 series airplanes had been manufactured

with .25-inch diameter holes, rather than the required radius slots, at the attach points. Radius slots at the panel attach points are required so that the panels can "blow out" (flexibly extend) when a differential pressure of .75 pounds per square inch (PSI) exists. Ceiling pressure relief panels having holes, rather than slots, at the attach points would not be capable of blowing out during a rapid decompression of the airplane. This condition, if not corrected, could result in the airplane not being able to withstand a rapid decompression caused by a hole below the compartment floor.

The FAA has reviewed and approved McDonnell Douglas MD–80 Service Bulletin 25–335, dated April 28, 1993, that describes procedures for inspecting the ceiling pressure relief panels in the forward, mid, and aft cargo compartments to determine if slotted attach points exist. The service bulletin provides instructions for modifying panels that do not have slotted attach points; this modification entails trimming material from the panel to create a slotted attach point.

Since an unsafe condition has been identified that is likely to exist or develop on other products of this same type design, the proposed AD would require inspection of the ceiling pressure relief panels to determine if slotted attach points are present, and modification of the panel(s), if necessary. The actions would be required to be accomplished in accordance with the service bulletin described previously.

There are approximately 1,016 Model DC–9–80 series airplanes and Model MD–88 airplanes of the affected design in the worldwide fleet. The FAA estimates that 556 airplanes of U.S. registry would be affected by this proposed AD. It would take approximately 1 work hour per airplane to accomplish the proposed inspection, at an average labor rate of $55 per work hour. Based on these figures, the total cost impact of the proposed inspection requirements of this AD on U.S. operators is estimated to be $30,580, or $55 per airplane. This total cost figure assumes that no operator has yet accomplished the proposed requirements of this AD action.

If modification of a panel is necessary, accomplishing the modification would entail approximately 5.4 work hours, at an average labor rate of $55 per work hour. No additional parts would be required. Based on these figures, the total cost of impact of any necessary modification is estimated to be $297 per panel.

The regulations proposed herein would not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. Therefore, in accordance with Executive Order 12612, it is determined that this proposal would not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

For the reasons discussed above, I certify that this proposed regulation (1) is not a "significant regulatory action" under Executive Order 12866; (2) is not a "significant rule" under the DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979); and (3) if promulgated, will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act. A copy of the draft regulatory evaluation prepared for this action is contained in the Rules Docket. A copy of it may be obtained by contacting the Rules Docket at the location provided under the caption **ADDRESSES.**

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Safety.

The Proposed Amendment

Accordingly, pursuant to the authority delegated to me by the Administrator, the Federal Aviation Administration proposes to amend 14 CFR part 39 of the Federal Aviation Regulations as follows:

PART 39—AIRWORTHINESS DIRECTIVES

1. The authority citation for part 39 continues to read as follows:

Authority: 49 U.S.C. App. 1354(a), 1421 and 1423; 49 U.S.C. 106(g); and 14 CFR 11.89.

§ 39.13 [Amended]

2. Section 39.13 is amended by adding the following new airworthiness directive:

McDonnell Douglas: Docket 93–NM–161–AD.

Applicability: Model DC–9–81 (MD–81), DC–9–82 (MD–82), DC–9–83 (MD–83), DC–9–87 (MD–87) series airplanes, and Model MD–88 airplanes; as listed in McDonnell Douglas MD–80 Service Bulletin 25–335, dated April 28, 1993; certificated in any category.

Compliance: Required as indicated, unless accomplished previously.

To ensure that the action of the cargo compartment ceiling relief panels will enable the airplane to withstand a rapid decompression caused by a hole below the compartment floor, accomplish the following:

(a) Within 18 months after the effective date of this AD, inspect the ceiling relief panels in the forward, mid, and aft cargo compartments to determine if slotted attach points are present, in accordance with McDonnell Douglas MD–80 Service Bulletin 25–335, dated April 28, 1993.

(1) If slotted attach points are present, no further action is required by this AD.

(2) If slotted attach points are not present on any panel, prior to further flight, modify that panel in accordance with the service bulletin.

(b) An alternative method of compliance or adjustment of the compliance time that provides an acceptable level of safety may be used if approved by the Manager, Los Angeles Aircraft Certification Office (ACO). Operators shall submit their requests through an appropriate FAA Principal Maintenance Inspector, who may add comments and then send it to the Manager, Los Angeles ACO.

Note: Information concerning the existence of approved alternative methods of compliance with this AD, if any, may be obtained from the Los Angeles ACO.

(c) Special flight permits may be issued in accordance with FAR 21.197 and 21.199 to operate the airplane to a location where the requirements of this AD can be accomplished.

Issued in Renton, Washington, on November 17, 1993.

James V. Devany,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 93–28680 Filed 11–22–93; 8:45 am]

BILLING CODE 4910–13–P

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14 CFR Part 73

[Airspace Docket No. 92–AWP–6]

Proposed Alteration and Subdivision of Restricted Area R–2503 and Revocation of R–2533; CA

AGENCY: Federal Aviation Administration (FAA), DOT..

ACTION: Notice of proposed rulemaking.

SUMMARY: This proposed rule would modify Restricted Area R–2503, Camp Pendleton, CA, and subdivide the area into three separate areas designated as R–2503A, R–2503B, and R–2503C. R–2503A would incorporate part of the existing Restricted Area R–2533, Oceanside, CA. R–2533 is proposed to be removed concurrent with this action. This proposal would allow Marine Corps Base Camp Pendleton to accomplish required training.

DATES: Comments must be received on or before January 10, 1994.

ADDRESSES: Send comments on the proposal in triplicate to: Manager, Air Traffic Division, AWP–500, Docket No.

92–AWP–6, Federal Aviation Administration, P.O. Box 92207, Worldway Postal Center, Los Angeles, CA 90009.

The official docket may be examined in the Rules Docket, Office of the Chief Counsel, room 916, 800 Independence Avenue, SW., Washington, DC, weekdays, except Federal holidays, between 8:30 a.m. and 5 p.m.

An informal docket may also be examined during normal business hours at the office of the Regional Air Traffic Division.

FOR FURTHER INFORMATION CONTACT: Diane Bodenhamer, Military Operations Program Office (ATM–420), Office of Air Traffic System Management, Federal Aviation Administration, 800 Independence Avenue, SW., Washington, DC 20591; telephone: (202) 267–3178.

SUPPLEMENTARY INFORMATION:

Comments Invited

Interested parties are invited to participate in this proposed rulemaking by submitting such written data, views, or arguments as they may desire. Comments that provide the factual basis supporting the views and suggestions presented are particularly helpful in developing reasoned regulatory decisions on the proposal. Comments are specifically invited on the overall regulatory, aeronautical, economic, and energy-related aspects of the proposal. Communications should identify the airspace docket number and be submitted in triplicate to the address listed above. Commenters wishing the FAA to acknowledge receipt of their comments on this notice must submit with those comments a self-addressed, stamped postcard on which the following statement is made: "Comments to Airspace Docket No. 92–AWP–6." The postcard will be date/time stamped and returned to the commenter. Send comments on environmental and land use aspects to: LT. Col. Robert Settle, Assistant Chief of Staff, Operations and Training (Airspace Management), Marine Corps Base, Camp Pendleton, CA 92055; telephone: (619) 725–8183.

All communications received on or before the specified closing date for comments will be considered before taking action on the proposed rule. The proposal contained in this notice may be changed in light of comments received. All comments submitted will be available for examination in the Rules Docket both before and after the closing date for comments. A report summarizing each substantive public contact with FAA personnel concerned with this rulemaking will be filed in the docket.

Availability of NPRM's

Any person may obtain a copy of this Notice of Proposed Rulemaking (NPRM) by submitting a request to the Federal Aviation Administration, Office of Public Affairs, Attention: Public Inquiry Center, APA–220, 800 Indendence Avenue SW., Washington, DC 20591, or by calling (202) 267–3485.

Communications must identify the notice number of this NPRM. Persons interested in being placed on a mailing list for future NPRM's should also request a copy of Advisory Circular No. 11–2A, which describes the application procedure.

The Proposal

The FAA is considering an amendment to part 73 of the Federal Aviation Regulations (14 CFR part 73) to subdivide Restricted Area R–2503, Camp Pendleton, CA, into three separate areas designated as R–2503A, R–2503B, and R–2503C. Camp Pendleton has found that having two restricted areas with similar sounding, but different numbers is confusing, and has requested that R–2533 be removed and modified under the designation of R–2503A. The proposed R–2503A is smaller in size than the current R–2533.The southwestern boundary of R–2503A would be two miles closer to shoreline so that the distance that nonparticipating aircraft would need to fly offshore to avoid the area would be reduced. Additionally, the boundary on the northwestern side of R–2503A would be adjusted to return airspace near San Clemente to the public. The proposed R–2503B is a slightly enlarged version of the current R–2503. The southwestern boundary would be moved one mile toward the shoreline to enable the Marine Corps to provide requisite training. The proposed R–2503C is new airspace which would extend from 15,000 to 27,000 feet and would overlie approximately three-fourths of the proposed R–2503B. The Marine Corps has requested this additional airspace to accomplish required training, such as high angle, high altitude artillery firing, and has indicated that its use will typically be less than 40 hours per year. A change to the using agency to standardize format is also included in this proposal. The coordinates for its airspace docket are based on North American Datum 83. Section 73.25 of part 73 of the Federal Aviation Regulations was republished in FAA Order 7400.8A dated March 3, 1993.

The FAA has determined that this proposed regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. It, therefore—(1) is not a "significant regulatory action" under Executive Order 12866; (2) is not a "significant rule" under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a regulatory evaluation as the anticipated impact is so minimal. Since this is a routine matter that will only affect air traffic procedures and air navigation, it is certified that this rule, when promulgated, will not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

Prior to a final decision, an environmental review is being conducted by the Department of Defense in compliance with the National Environmental Policy Act of 1969 (NEPA).

List of Subjects in 14 CFR Part 73

Airspace, Navigation (air).

The Proposed Amendment

In consideration of the foregoing, the Federal Aviation Administration proposes to amend 14 CFR part 73 as follows:

PART 73—[AMENDED]

1. The authority citation for part 73 continues to read as follows:

Authority: 49 U.S.C. app. 1348(a), 1354(a), 1510, 1522; E.O. 10854, 24 FR 9565, 3 CFR, 1959–1963 Comp., p. 389; 49 U.S.C. 106(g); 14 CFR 11.69.

§ 73.25 [Amended]

2. § 73.25 is amended as follows:

R–2503 Camp Pendleton, CA [Removed]

R–2503A Camp Pendleton, CA [New]

Boundaries. Beginning at lat. 33°22'42"N., long. 117°36'45"W.; to lat. 33°27'13"N., long. 117°34'17"W.; to lat. 33°18'41"N., long. 117°23'58"W.; to lat. 33°17'30"N., long. 117°16'43"W.; to lat. 33°14'09"N., long. 117°26'38"W.; to the point of beginning by following a line 1 NM from and parallel to the shoreline.

Designated altitudes. Surface to 2,000 feet MSL.

Time of designation. 0600–2400 local time daily; other times by NOTAM.

Controlling agency. FAA, Los Angeles ARTCC.

Using agency. U.S. Marine Corps, Commanding Officers, MCB Camp Pendleton, CA.

R–2503B Camp Pendleton, CA [New]

Boundaries. Beginning at lat. 33°24′23″N., long, 117°15′18″W.; to lat. 33°18′00″N., long, 117°16′11″W.; to lat. 33°17′30″N., long, 117°16′43″W.; to lat. 33°18′41″N., long, 117°23′58″W.; to lat. 33°27′13″N., long, 117°34′17″W.; to lat. 33°30′13″N., long, 117°29′16″W.; to the point of beginning.

Designated altitudes. Surface to 15,000 feet MSL.

Time of designation. 0600–2400 local time daily; other times by NOTAM.

Controlling agency. FAA, Los Angeles ARTCC.

Using agency. U.S. Marine Corps, Commanding Officer, MCB Camp Pendleton, CA.

R–2503C Camp Pendleton, CA [New]

Boundaries. Beginning at lat. 33°24′23″N., long, 117°15′18″W.; to lat. 33°18′41″N., long, 117°23′58″W.; to lat. 33°27′13″N., long, 117°34′17″W.; to lat. 33°30′13″N., long, 117°29′16″W.; to the point of beginning.

Designated altitudes. 15,000 feet MSL to FL 270.

Time of designation. Intermittent by NOTAM at least 24 hours in advance, and with the concurrence of the controlling agency.

Controlling agency. FAA, Los Angeles ARTCC.

Using agency. U.S. Marine Corps, Commanding Officer, MCB Camp Pendleton, CA.

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R–2533 Oceanside, CA [Removed]

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Issued in Washington, DC, on November 15, 1993.

Harold W. Becker,

Manager, Airspace-Rules and Aeronautical Information Division.

[FR Doc. 93–28717 Filed 11–22–93; 8:45 am]

BILLING CODE 4910–13–M

DEPARTMENT OF STATE

Bureau of Consular Affairs

22 CFR Part 41

[Public Notice 1905]

Visas: Documentation of Nonimmigrants Under the Immigration and Nationality Act; Temporary Visitors for Business or Pleasure

AGENCY: Bureau of Consular Affairs, DOS.

ACTION: Proposed rule; extension of comment period.

SUMMARY: This document extends to December 6, 1993 the comment period regarding the proposed changes to B visa regulations. The proposed rulemaking, published on July 26, 1993, 56 FR 40024, reflects changes in the interpretation of the B visa classification, temporary visitors for business and/or pleasure resulting from the enactment of the Immigration Act of 1990 (IMMACT 90).

DATES: Written comments must be received in duplicate on or before December 6, 1993.

ADDRESSES: Interested persons are invited to submit comments in duplicate to Chief, Division of Legislation and Regulations, Visa Office, Department of State, Washington, DC 20522–0113.

FOR FURTHER INFORMATION CONTACT: Stephen K. Fischel, Chief, Legislation and Regulations Division, Visa Office, Washington, DC, 20522–0113, (202) 663–1204.

SUPPLEMENTARY INFORMATION: The Immigration Act of 1990 (Pub. L. 101–649, Nov. 29, 1990) with subsequent modification by the Miscellaneous and Technical Immigration and Naturalization Amendments of 1991 (MATINA) (Pub. L. 102–232, Dec. 12, 1991) amended certain exisiting nonimmigrant visa classifications in the Immigration and Nationality Act of 1952, (INA), and added several new ones. IMMACT 90 and MATINA did not directly amend the INA's B visa classification (INA 101(a)(15)(B)), but certain changes to the H–1B visa classification (INA 101(a)(15)(H)(i)(b)) and the creation of the new O, P, and R classifications by IMMACT 90 affect the interpretation of the B visa classification currently set forth in the FAM. Proposed rulemaking 1840 concerns an extremely significant visa classification. In view of the importance of the subject matter, and to coincide with INS' comment period, the Department is extending the comment period through December 6, 1993 to provide the public with ample time to submit comments.

Dated: November 17, 1993.

David L. Hobbs,

Acting Assistant Secretary for Consular Affairs.

[FR Doc. 93–28838 Filed 11–22–93; 8:45 am]

BILLING CODE 4710–06–P

DEPARTMENT OF THE INTERIOR

Office of Surface Mining Reclamation and Enforcement

30 CFR Parts 701, 784 and 817

RIN: 1029–AB69

Definitions of "Anthracite," "Bituminous/Subbituminous," "Coal," and "Lignite"

AGENCY: Office of Surface Mining Reclamation and Enforcement, Interior.

ACTION: Notice of public hearings.

SUMMARY: The Office of Surface Mining Reclamation and Enforcement (OSM) of the U.S. Department of the Interior (DOI) published a proposed rule which would revise the existing definitions of "anthracite" and "coal"; add definitions of "bituminous/subbituminous" and "lignite"; and remove the existing definitions of "anthracite, bituminous and subbituminous coal" and "lignite coal." OSM has received requests to hold public hearings on the proposed rule and is announcing that public hearings will be held.

DATES: Public hearings are scheduled for: November 29, 1993, in Washington, DC, at 9:30 a.m. local time and December 6, 1993, in Jackson, CA, at 9 a.m. local time.

ADDRESSES: The public hearings will be held at the South Interior Building Room 220, 1951 Constitution Ave. NW., Washington, DC and the Amador Inn's Gold Room located in Denny's Restaurant, 200 South Highway 49, Jackson, CA.

FOR FURTHER INFORMATION CONTACT: Douglas J. Growitz, P.G., Branch of Research and Technical Standards, Office of Surface Mining Reclamation and Enforcement, room 640, 1951 Constitution Avenue, NW, Washington, DC 20240; Telephone: 202–343–1507.

SUPPLEMENTARY INFORMATION: On October 7, 1993 (58 FR 52374), OSM published a proposed rule which would revise the existing definitions of "anthracite" and "coal"; add definitions of "bituminous/subbituminous" and "lignite"; and remove the existing definitions of "anthracite, bituminous and subbituminous coal" and "lignite coal." OSM proposes to change the existing definition of "coal" and its related terms by deleting references to the coal classifications of ASTM Standard D 388–77. These revisions will avoid prior periodic calls to update the existing definitions to reflect the most current ASTM Standard D 388.

OSM has received requests to hold public hearings on the proposed rule.

As a result, OSM has scheduled public hearings on the proposed definition of coal rule in Washington, DC; and Jackson, California. Refer to **DATES** and **ADDRESSES** for the times, dates and locations for each hearing. The hearings will continue until all persons wishing to testify have been heard. To assist the transcriber and ensure an accurate record, OSM requests that persons who testify at a hearing give the transcriber a written copy of their testimony.

Any disabled individual who has need for a special accommodation to attend a public hearing should contact the individual listed under **FOR FURTHER INFORMATION CONTACT.**

Dated: November 18, 1993.

Brent Wahlquist,

Assistant Director, Reclamation and Regulatory Policy.

[FR Doc. 93–28761 Filed 11–22–93; 8:45 am]

BILLING CODE 4310–05–M

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30 CFR Part 934

North Dakota Permanent Regulatory Program

AGENCY: Office of Surface Mining Reclamation and Enforcement (OSM), Interior.

ACTION: Proposed rule; public comment period and opportunity for public hearing on proposed amendment.

SUMMARY: OSM is announcing the receipt of a proposed amendment to the North Dakota permanent regulatory program (hereinafter, the "North Dakota program") under the Surface Mining Control and Reclamation Act of 1977 (SMCRA). The amendment consists of proposed changes in the State's preblast survey requirements and the Small Operator Assistance Program rules.

This document sets forth the times and locations that the North Dakota program and proposed amendment to that program are available for public inspection, the comment period during which interested persons may submit written comments on the proposed amendment, and procedures that will be followed regarding the public hearing, if one is requested.

DATES: Written comments must be received by 4 p.m., m.s.t. December 23, 1993. If requested, a public hearing on the proposed amendment will be held on December 20, 1993. Requests to present oral testimony at the hearing must be received by 4 p.m., m.s.t. on December 8, 1993.

ADDRESSES: Written comments should be mailed or hand delivered to Guy Padgett at the address listed below.

Copies of the North Dakota program, the proposed amendment, and all written comments received in response to this notice will be available for public review at the addresses listed below during normal business hours, Monday through Friday, excluding holidays. Each requester may receive one free copy of the proposed amendment by contacting OSM's Casper Field Office.

Guy Padgett, Director, Casper Field Office; Office of Surface Mining Reclamation and Enforcement; 100 East B Street, room 2128; Casper, WY 82601–1918 (307) 261–5776.

Mr. Edward J. Englerth, Director, Reclamation Division; North Dakota Public Service Commission, Capitol Building; Bismarck, North Dakota 58505–0165 (701) 224–4092.

FOR FURTHER INFORMATION CONTACT: Guy V. Padgett, Telephone: (307) 261–5776.

SUPPLEMENTARY INFORMATION:

I. Background on the North Dakota Program

On December 15, 1980, the Secretary of the Interior conditionally approved the North Dakota program as administered by the North Dakota Public Service Commission. General background information on the North Dakota program, including the Secretary's findings, the disposition of comments, and conditions of approval of the North Dakota program can be found in the December 15, 1980 **Federal Register** (45 FR 82214). Subsequent actions concerning North Dakota's program and program amendments can be found at 30 CFR 934.15 and 934.16.

II. Proposed Amendment

By letter dated October 26, 1993, (Administrative Record No. ND–T–01) North Dakota submitted a proposed amendment to its permanent program pursuant to SMCRA. The North Dakota proposed amendment is required in order to implement changes in North Dakota's reclamation law approved by the 1993 State Legislative Assembly.

(1) North Dakota Administrative Code (NDAC) 69–05.2–17–02. North Dakota is proposing to increase the distance standard required for pre-blast surveys from ½ mile (0.85 kilometers) to 1 mile (1.61 kilometers).

(2) NDAC Chapter 69–05.2–29 [Small Operator Assistance]. North Dakota proposes to make changes throughout Chapter 29 of its Administrative Code to conform with amendments made by the 1993 Legislative Assembly to Section 38–14.1–37 of the North Dakota Century Code (NDCC). The proposed changes include: (1) Expanding the services available to small operators to include those listed in NDCC 38–14.1–37(2); (2) increasing the annual production limit for small operators from 100,000 tons to 300,000 tons and limiting eligibility to those operations that would be required to pay reclamation fees under SMCRA; (3) revising the overproduction conditions under which an operator might be subject to reimbursement of program expenses to production in excess of 300,000 tons in the twelve months following issuance of a mining permit; (4) limiting the conditions under which the reimbursement obligation can be waived due to applicant good faith to cases where the applicant fails to submit a permit application or where the applicant fails to mine after obtaining a permit; and (5) changing the description of entities that perform such services from "laboratories" to "public or private entities."

III. Public Comment Procedures

In accordance with the provisions of 30 CFR 732.17(h), OSM is seeking comments on whether the proposed amendment satisfies the applicable program approval criteria of 30 CFR 732.15. If the amendment is deemed adequate, it will become part of the North Dakota program.

Written Comments

Written comments should be specific, pertain only to the issue proposed in this rulemaking, and include explanations in support of the commentor's recommendations. Comments received after the time indicated under **DATES** or at locations other than the Casper Field Office will not necessarily be considered in the final rulemaking or included in the administrative record.

Public Hearing

Persons wishing to testify at the public hearing should contact the person listed under **FOR FURTHER INFORMATION CONTACT** by 4 p.m., m.s.t. December 8, 1993. The location and time of the hearing will be arranged with those persons requesting the hearing. If no one requests an opportunity to testify at the public hearing, the hearing will not be held.

Filing of a written statement at the time of the hearing is requested as it will greatly assist the transcriber. Submission of written statements in advance of the hearing will allow OSM officials to prepare adequate responses and appropriate questions.

The public hearing will continue on the specified date until all persons scheduled to comment have been heard. Persons in the audience who have not

been scheduled to testify, and who wish to do so, will be heard following those who have been scheduled. The hearing will end after all persons scheduled to testify and persons present in the audience who wish to testify have been heard.

Public Meeting

If only one person requests an opportunity to testify at a hearing, a public meeting, rather than a public hearing, may be held. Persons wishing to meet with OSM representatives to discuss the proposed amendment may request a meeting at the OSM office listed under **FOR FURTHER INFORMATION CONTACT.** All such meetings will be open to the public and, if possible, notices of meetings will be posted at the locations listed under **ADDRESSES.** A written summary of each meeting will be made a part of the administrative record.

IV. Procedural Determinations

Compliance With Executive Order 12866

This proposed rule is exempted from review by the Office of Management and Budget (OMB) under Executive Order 12866.

Compliance With Executive Order 12778

The Department of the Interior has conducted the reviews required by section 2 of Executive Order 12778 (Civil Justice Reform) and has determined that this rule meets the applicable standards of subsection (a) and (b) of that section. However, these standards are not applicable to the actual language of State regulatory programs and program amendments since each such program is drafted and promulgated by a specific State, not by OSM. Under sections 503 and 505 of SMCRA (30 U.S.C. 1253 and 1255) and 30 CFR 730.11, 732.15, and 732.17(h)(10), decisions on proposed State regulatory programs and program amendments submitted by the States must be based solely on a determination of whether the submittal is consistent with SMCRA and its implementing Federal regulations and whether the requirements of 30 CFR parts 730, 731, and 732 have been met.

Compliance With the National Environmental Policy Act

No environmental impact statement is required for this rule since section 702(d) of SMCRA (30 U.S.C. 1292(d)) provides that agency decisions on proposed State regulatory program provisions do not constitute major Federal actions within the meaning of section 102(2)(C) of the National Environmental Policy Act, 42 U.S.C. 4332(2)(C).

Paperwork Reduction Act

This rule does not contain information collection requirements that require approval by the Office of Management and Budget under the Paperwork Reduction Act, 44 U.S.C. 3507 *et seq.*

Compliance With the Regulatory Flexibility Act

The Department of the Interior has determined that this rule will not have a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*). The State submittal which is the subject of this rule is based upon counterpart Federal regulations for which an economic analysis was prepared and certification made that such regulations would not have a significant economic effect upon a substantial number of small entities. Hence, this rule will ensure that existing requirements previously promulgated by OSM will be implemented by the State. In making the determination as to whether this rule would have a significant economic impact, the Department relied upon the data and assumptions for the counterpart Federal regulations.

List of Subjects in 30 CFR Part 926

Intergovernmental relations, Surface mining, Underground mining.

Dated: November 9, 1993.

Raymond L. Lowrie,

Assistant Director, Western Support Center.

[FR Doc. 93–28701 Filed 11–22–93; 8:45 am]

BILLING CODE 4310–05–M

Notices

Federal Register
Vol. 58, No. 224
Tuesday, November 23, 1993

This section of the FEDERAL REGISTER contains documents other than rules or proposed rules that are applicable to the public. Notices of hearings and investigations, committee meetings, agency decisions and rulings, delegations of authority, filing of petitions and applications and agency statements of organization and functions are examples of documents appearing in this section.

DEPARTMENT OF AGRICULTURE

Cooperative State Research Service

Committee of Nine; Meeting

In accordance with the Federal Advisory Committee Act of October 6, 1972, (Public Law 92–463, 86 Stat. 770–776), the Cooperative State Research Service announces the following meeting:

Name: Committee of Nine.
Date: December 1, 1993.
Time: 11 a.m., EST.
Place: Room 346, 901 D Street SW., USDA, CSRS, Washington, DC.
Type of Meeting: Conference call. Open to the public. Persons may participate in the meeting as time and space permit.
Comments: The public may file written comments before or after the meeting with the contact person listed below.
Purpose: To evaluate and recommend proposals for cooperative research on problems that concern agriculture in two or more States, and to make recommendations for allocation of regional research funds appropriated by Congress under the Hatch Act for research at the State Agricultural Experiment Stations.
Contact Person for Agenda and More Information: Dr. Walter R. Woods, Executive Secretary, U.S. Department of Agriculture, Cooperative State Research Service, room 346, Aerospace Building, Washington, DC 20250, Telephone: 202–401–6040.

Done at Washington, DC this 9th day of November, 1993.

William D. Carlson,

Associate Administrator, Cooperative State Research Service.

[FR Doc. 93–28675 Filed 11–22–93; 8:45 am]

BILLING CODE 3410–22–M

DEPARTMENT OF COMMERCE

International Trade Administration

(A–570–822)

Amended Final Determination and Amended Antidumping Duty Order: Certain Helical Spring Lock Washers From the People's Republic of China

AGENCY: Import Administration, International Trade Administration, Department of Commerce.

EFFECTIVE DATE: November 23, 1993.

FOR FURTHER INFORMATION CONTACT: Bill Crow, Office of Antidumping Investigations, Import Administration, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue, NW., Washington, DC 20230; telephone: (202) 482–0116.

Amended Final Determination and Amended Antidumping Duty Order

We are amending the final determination of sales at less than fair value, and the antidumping duty order, of helical spring lock washers (HSLWs) from the People's Republic of China (PRC), to reflect the correction of ministerial errors made in the margin calculation in the final determination.

Case History

In accordance with section 735(a) of the Tariff Act of 1930, as amended (19 U.S.C. 1673d(a)) (the Act), on September 20, 1993, the Department of Commerce (the Department) published its final determination that HSLWs from the PRC were being sold at less than fair value (58 FR 48833). On September 27, 1993, respondent, Hangzhou Spring Washer Plant (HSWP), alleged that the Department made several clerical errors in its final determination regarding the margin calculations and requested that the Department correct these errors. On October 4, 1993, petitioner, Shakeproof Industrial Products Division of Illinois Tool Works, Inc., submitted its comments on respondent's allegations. On October 8, 1993, in accordance with section 735(d) of the Act, the International Trade Commission (ITC) notified the Department that an industry in the United States is threatened with material injury by reason of such imports. The ITC did not determine, pursuant to section 735(b)(4)(B) of the Act, that but for the suspension of liquidation of entries of certain HSLWs from the PRC, the domestic industry would have been materially injured. In accordance with section 736(a) of the Act, on October 19, 1993, the Department published its antidumping duty order directing the assessment of antidumping duties of certain HSLWs from the PRC (58 FR 53914).

Scope of Order

For purposes of this investigation, certain HSLWs are circular washers of carbon steel, of carbon alloy steel, or of stainless steel, heat-treated or non heat-treated, plated or non-plated, with ends that are off-line. HSLWs are designed to: (1) Function as a spring to compensate for developed looseness between the component parts of a fastened assembly; (2) distribute the load over a larger area for screws or bolts; and (3) provide a hardened bearing surface. The scope does not include internal or external tooth washers, nor does it include spring lock washers made of other metals, such as copper. The lock washers subject to this investigation are currently classifiable under subheading 7318.21.0000 of the Harmonized Tariff Schedule of the United States (HTSUS). Although the HTSUS subheadings are provided for convenience and customs purposes, our written description of the scope of this investigation is dispositive.

Amended Final Determination

On September 27, 1993, respondent alleged that the Department had made six ministerial errors in the final calculation performed to determine the margin for HSWP in accordance with section 353.28 of the Department's regulations. Each alleged error is discussed separately below.

Comment 1

Chemical usage was reported at different concentration levels for the two separate production processes used to make finished HSLWs: the HSLW manufacturing process and the plating process. Respondent claims that the Department failed to adjust the hydrochloric acid price used in the plating process to reflect a 33–35 percent concentration level. Moreover, respondent also states that the Department failed to adjust the prices of hydrogen fluoride and nitric acid to reflect their concentration levels as used by HSWP's plating subcontractor.

Petitioner states that this is not a clerical error. Petitioner notes that respondent refers to submissions and not its case brief. Additionally, petitioner asserts that it did not find any specific reference in respondent's case brief to this issue and it is not clear why this issue is now being raised.

DOC Position

We agree with respondent that the Department erred in not adjusting the prices of hydrochloric acid and hydrogen fluoride to reflect the 33–35 percent and 55 percent concentration levels, respectively, used in the plating process. In our final determination, we indicated that we would adjust chemical prices to reflect their concentration levels. We did this for hydrochloric acid used in the HSLW manufacturing process. However, we inadvertently omitted accounting for the concentration levels of hydrochloric acid and hydrogen fluoride used in the plating process. We disagree with petitioner that this issue could only be addressed in the briefing process; these omissions constitute an error in the mathematics of our margin calculation. These were ministerial oversights, and we have made the necessary corrections (see below).

We disagree with respondent that the price of nitric acid should be recalculated to reflect its concentration level. In its March 16, 1993, response, respondent does not give a concentration level. The response states only that the nitric acid used in the plating process is in a very low consistency. Thus, this is not a clerical error as such, but is a methodological decision by the Department.

Comment 2

Respondent notes that the Department considered respondent's statements that the Indian import prices were considerably higher than other sources such as a U.S. Consulate quote from the Chrome plated Lug Nuts from the PRC (Lug Nuts) case and a quote from the U.S. spot market. Respondent also notes that despite the lower prices, the Indian import statistics for hydrochloric acid were used because the U.S. Consulate quote from the Lug Nuts case was not 1000 percent lower than the Indian import figure when the U.S. Consulate quote is adjusted for the concentration level of the chemical as used by respondent. Respondent states that it is a clerical error to make this comparison of Indian import statistics to the U.S. Consulate quote by adjusting only one half of the equation for chemical concentration level. Respondent argues that neither the Indian import statistics nor the U.S. Consulate quote carry a chemical concentration level. Respondent states that the Department's comparison of Indian import statistics to other sources, such as the U.S. Consulate quote, should be made by multiplying both figures by the concentration level of the chemical as used by respondent. Respondent argues that such an equation will yield a difference of over 1000 percent, and that the Department should therefore use the U.S. Consulate quote from the Lug Nuts case to value respondent's hydrochloric acid usage for both production and plating costs.

Petitioner states that this is not a ministerial error. Petitioner contends that respondent's allegation is based on assumptions which were not contained in its case brief.

DOC Position

We disagree with respondent. In our final determination, we examined the prices for hydrochloric acid in the cable rrom our consulate in Pakistan, which shows the price in Pakistani Rupees per kilogram. We also examined the recommended source for contemporary U.S. spot market prices. We noted in our final determination that a difference between two source prices of greater than 1000 percent warranted stricter scrutiny by the Department. This percentage was a benchmark which we used together with other factors in examining the alternatives before the Department; this was not, and is not, a determinative rule per se. In its allegation of clerical errors, respondent frames its arguments concerning hydrochloric acid in terms of the percentage difference in the prices from different sources. We therefore note that in our analysis the value derived from the India import statistics is not over 1000 percent higher than the values reported in either alternative source. According to our analysis only the import statistics value must first be multiplied by 31 percent, the concentration of hydrochloric acid in the solution actually employed in making HSWP's HSLW.

Our analysis of valuing hydrochloric acid was based on our interpretation that the value of the chemical in the cable represented hydrochloric acid in an industrial solution while the Indian import statistics represented bulk quantities at or near 100 percent consistency. We determined that in this particular instance, we would use the Indian import statistics to value hydrochloric acid. We determined that the divergence of the Indian import value is not so significantly different from other indicators, both contemporary world market prices and Indian domestic prices, that we must rely on the data reported in the investigation of Lug Nuts, adjusted for inflation. Thus, in our final determination, to value hydrochloric acid, we used the 1991 Indian Import Statistics, adjusted for inflation. This is not a clerical error as such, but is a methodological decision by the Department.

Comment 3

Respondent claims that it is a clerical error for the Department to have used the much more expensive anhydrous form rather than the standard aqueous solution form of sodium hydroxide because most chemicals are purchased and used in an aqueous solution. Respondent states that in its March 16, 1993, submission it reported a list of chemicals and their concentration characteristics, and in some cases, whether the chemical was in its solid or anhydrous form.

Petitioner asserts that this is not a clerical error. Petitioner contends that respondent's allegation is based on assumptions which were not contained in its case brief.

DOC Position

We disagree with respondent. In our September 13, 1993, final concurrence memorandum, we used the 1991 Indian import statistics for all solid sodium hydroxide to value sodium hydroxide (NaOH). We noted that both the HSLW platers and the Indian Import statistics specifically refer to separate uses of NaOH by the two terms "soda lye" and "sodium hydroxide." The differences between the soda lye used in the production process and the highly concentrated sodium hydroxide formula used for plating include such elements as purity, form, and consistency. We determined that using the two specific import categories reflects any such outstanding differences in physical characteristics. Thus, this is not a clerical error as such, but is a methodological decision by the Department.

Comment 4

Respondent argues that in valuing caustic soda the Department has arbitrarily assigned a 15 percent concentration level to Indian imports of this chemical. Respondent further contends that the Department chose this concentration level because it was the lowest concentration reported by respondent for this chemical. Respondent maintains that caustic soda is generally traded at a 50 percent concentration and sometimes shipped

internationally at a higher 73–76 percent concentration. Respondent contends that the Department was not consistent in assigning concentration levels to the chemicals that it valued.

Petitioner asserts that this is not a clerical error. Petitioner contends that respondent's allegation is based on assumptions which were not on the record.

DOC Position

We disagree with respondent. On page 14 of the March 16, 1993, submission, respondent reported a concentration level of 15 percent for caustic soda used in the plating process. Based on that submission, in the final determination we adjusted the value of caustic soda to reflect the 15 percent concentration. Because we used information on the record and we intended to do so, this is not a clerical error as such, but is a methodological decision by the Department.

Comment 5

Respondent argues that the Department should have calculated the processed wire usage using the figure for all green wire used during the period of investigation (POI) rather than a figure representing U.S. sales of HSLWs during the POI. Respondent argues that the use of a figure representing all green wire rod consumption would more clearly reflect actual processed wire usage and would corroborate the Department's verification finding that there was only a small amount of processed wire in evidence at the plant during verification.

Petitioner states that this is not a clerical error. Petitioner believes that this is a question of the methodology used and is not an error in the margin calculations.

DOC Position

We agree with petitioner. In our September 13, 1993, final concurrence memorandum, we stated that respondent failed to report the use of processed wire in a timely manner, and that, therefore, we do not have the information regarding the consumption of processed wire vis-a-vis HSWP's various markets. We noted at verification that the inspection of the current inventory showed that almost all of the raw steel was green wire rod. We also stated that this was a general indication that the processed wire purchased for production during the POI is no longer being purchased. We made the adverse assumption that this is a result of HSWP's verified declining sales and shipments to the United States resulting from this investigation. Thus, this is not a clerical error as such, but is a methodological decision by the Department.

Comment 6

Respondent argues that it is a clerical error for the Department to choose the selling, general & administrative expenses (SG&A) figure found in the August 3, 1993, cable from the U.S. Consulate in India, when there was publicly available published information on the record (*i.e.*, the industry average published by the Reserve Bank of India).

Petitioner states that this is not a clerical error. Petitioner believes that this is a question of the selection of a production input, not an error in the margin calculations.

DOC Position

We agree with petitioner. In our final determination, we used 30 percent to establish HSWP's SG&A. According to the cable sent by the U.S. Consulate in Bombay for this investigation, 30 percent represents the SG&A expense of Forbes Gokak, the only Indian producer of HSLWs. We determined that this degree of specificity was more important than the fact that the other two sources were published and publicly available (the Reserve Bank of India Bulletin and the Official Directory of the Stock Exchange of India). Thus, this is not a clerical error as such, but is a methodological decision by the Department.

Accordingly, pursuant to section 735(e) of the Act, we have corrected the ministerial errors in the final determination of sales at less than fair value by recalculating the prices in the plating process for a 34 percent concentration level of hydrochloric acid, thus, using the average of the 33–35 percent range reported for hydrochloric acid by the respondent, and recalculating the price of hydrogen fluoride to represent a 55 percent consistency. The final estimated margin changes from 77.47 percent published in the final determination of sales at less than fair value of HSLWs from the HSWP and for all exports by HSWP's through its named market trading companies to 69.88 percent. The "All Others" rate does not change from the 128.63 percent published in the final determination.

Amended Antidumping Duty Order

In accordance with section 736 of the Act, the Department will direct Customs officers to assess, upon further advice by the administrating authority pursuant to section 736(a)(1) of the Act, antidumping duties equal to the amount by which the foreign market value of the merchandise exceeds the U.S. price for all entries of certain HSLWs from the PRC. These antidumping duties will be assessed on all unliquidated entries of certain HSLWs from the PRC entered, or withdrawn from warehouse, for consumption on or after October 15, 1993. U.S. Customs officers must require, at the same time as importers would normally deposit estimated duties, the following cash deposits for the subject merchandise:

Manufacturer/producer/exporter	Margin percentage
Hangzhou Spring Washer Plant	69.88
Hangzhou via IFI Morgan Limited	69.88
Hangzhou via Carway Development Limited	69.88
Hangzhou via Midway Fasteners Ltd.	69.88
Hangzhou via Linkwell Industry Co., Ltd.	69.88
Hangzhou via Fastwell Industry Co., Ltd.	69.88
Hangzhou via Sunfast International Corp.	69.88
Hangzhou via Winner Standard Parts Co., Ltd.	69.88
All Others	128.63

This notice constitutes the amended final determination and amended antidumping duty order with respect to HSLWs from the PRC, pursuant to section 736(a) of the Act. Interested parties may contact the Central Records Unit, room B–099 of the Main Commerce Building, for copies of an updated list of antidumping duty orders currently in effect.

This amended final determination and amended antidumping duty order is published in accordance with section 735(e) and 736(a) of the Act and 19 CFR 353.21 and 353.28.

Dated: November 17, 1993.

Barbara R. Stafford,

Acting Assistant Secretary for Import Administration.

[FR Doc. 93–28753 Filed 11–22–93; 8:45 am]

BILLING CODE 3510–DS–P

[A–437–601]

Tapered Roller Bearings and Parts Thereof, Finished and Unfinished, From the Republic of Hungary; Preliminary Results of Antidumping Administrative Review

AGENCY: International Trade Administration/Import Administration.

ACTION: Notice of preliminary results of the antidumping duty administrative review of tapered roller bearings and

parts thereof, finished and unfinished, from the Republic of Hungary.

SUMMARY: In response to a request by the respondent, Magyar Gordulocsapagy Muvek, the Department of Commerce is conducting an administrative review of the antidumping duty order on tapered roller bearings and parts thereof, finished and unfinished, from the Republic of Hungary. The review covers shipments of this merchandise to the United States during the period June 1, 1991 through May 31, 1992. The review indicates the existence of dumping margins during the period of review.

As a result of this review, we have preliminarily determined to assess antidumping duties equal to the difference between United States price and foreign market value. Interested parties are invited to comment on these preliminary results.

EFFECTIVE DATE: November 23, 1993.

FOR FURTHER INFORMATION CONTACT: Breck Richardson or Maureen Flannery, Office of Antidumping Compliance, Import Administration, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue, NW., Washington DC 20230; telephone (202) 482–0648.

Background

On June 8, 1992, the Department of Commerce (the Department) published in the **Federal Register** (57 FR 24244) a notice of opportunity to request an administrative review of the antidumping duty order on tapered roller bearings and parts thereof, finished and unfinished, (TRBs) from Hungary (52 FR 23319, June 19, 1987). On June 30, 1992, the respondent, Magyar Gordulocsapagy Muvek (MGM), requested that we conduct an administrative review in accordance with 19 CFR 353.22(a). We published a notice of initiation of this antidumping duty administrative review on July 22, 1992 (57 FR 32521). The Department is conducting the administrative review in accordance with section 751 of the Tariff Act of 1930, as amended (the Act). From September 13 through September 20, 1993, we conducted a verification of MGM's responses.

Scope of Review

Imports covered by this review are shipments of TRBs and parts thereof, finished and unfinished, from Hungary. This merchandise is classifiable under the *Harmonized Tariff Schedule* (HTS) item numbers 8482.20.00, 8482.91.00.60, 8482.99.30, 8483.20.40, 8483.20.80, 8483.30.80, 8483.90.20, 8483.90.30 and 8483.90.80. Although the HTS item numbers are provided for convenience and customs purposes, our written description of the scope of this proceeding is dispositive.

This review covers one manufacturer/exporter of Hungarian TRBs and the period June 1, 1991, through May 31, 1992. MGM accounts for all Hungarian exports to the United States of the subject merchandise.

United States Price

We based the United States price on purchase price, in accordance with section 772(b) of the Act, because the subject merchandise was sold to unrelated purchasers in the United States prior to importation into the United States. Purchase price was based on the FOB Hamburg port price to unrelated purchasers. Deductions were made for brokerage and handling and foreign inland freight charges. The brokerage and handling charges were paid in convertible currency. We valued foreign inland freight deductions using surrogate data based on Mexican freight costs. We selected Mexico as the surrogate country for the reasons explained in the "Foreign Market Value" section of this notice.

Foreign Market Value

In the most recent review of this order, the Department treated Hungary as a non-market-economy country. None of the parties to this proceeding has contested such treatment in this review. We have calculated foreign market value in accordance with section 773(c) of the Act and section 353.52 of the Department's regulations. Section 773(c) of the Act requires us to base foreign market value on a valuation of the factors of production in a market economy country that is at a level of development comparable to that of the non-market-economy country and is a significant producer of comparable merchandise. Based on these criteria, we determined that South Africa, Uruguay, Algeria, Malaysia and Mexico would be appropriate surrogates for Hungary.

We chose Mexico as the surrogate for valuing the factors of production because we were able to obtain from Mexico more complete publicly available data than from the other countries. It is the Department's practice to value factor of production inputs from publicly available sources in a market economy, where possible (*see Final Determination of Sales at Less Than Fair Value: Certain Helical Spring Lock Washers from the People's Republic of China*, 58 FR 48833, September 20, 1993). We valued the factors of production as follows:

- Certain raw material costs were valued based on MGM's imports of steel products from market economies which were paid for in freely convertible currency.
- In the absence of market economy prices paid by MGM, we valued other raw material inputs using the 1991 and 1992 publications of Schedule B Commodity by Country (U.S. Department of Commerce: Economics and Statistics Administration—Bureau of the Census). The information we obtained from this publication was for F.A.S. export data on hot-rolled steel, cold-rolled steel, and steel alloy scrap.
- We applied the values we obtained for materials to the factors of production reported by MGM, some of which were adjusted in accordance with our findings at verification. The material cost for each component was determined by multiplying the gross weight of steel used in the production of that component by the price of steel (based on weight) and then deducting an amount for saleable scrap. Because MGM was unable at verification to provide sufficient evidence to support its claimed scrap adjustment for certain sales, we only allowed a scrap credit in those cases where we could verify MGM's claimed saleable scrap. The scrap factor was calculated as the difference between the weight of the steel input (the gross weight) and the weight of the component (the net weight). We adjusted the scrap factor downward to account for waste and burn-off. Saleable scrap value was determined by applying a surrogate scrap value to the adjusted scrap factor. The steel costs we used were derived from two sources: Public information on Mexican imports of steel from the United States and actual imports of steel by MGM from western European countries at costs incurred in market-based currencies. Adjustments were made to some of the import pricing information as well as to some of the reported gross and net weights based on information learned during the verification of MGM's response.
- We valued both inland freight for the finished TRBs and inland freight on the steel inputs using publicly available Mexican freight rates. This information was taken from data obtained from the Mexican Freight Transportation Industry Chamber.
- We used actual brokerage and handling charges since those charges were incurred in a freely convertible currency.
- We valued direct labor using a 1991 Mexican labor rate for the manufacture of fabricated metal products, except machinery and equipment. This rate

was obtained from the Book of Labour Statistics, published by the International Labour Office (ILO). This ILO rate includes basic salaries, "payments in respect of time paid for but not worked, bonuses and gratuities, the cost of food, drink and other payments in kind, cost of workers' housing borne by employers, employers' social security expenditures, cost to the employer for vocational training, welfare services and miscellaneous items, such as transport of workers, work clothes and recruitment, together with taxes regarded as labour cost" in Mexico.

- The labor cost for each component was calculated by multiplying the total labor minutes by the surrogate labor rate.
- Publicly available data regarding overhead were not available, so we had to resort to a range of factory overhead and indirect labor rates from a number of roller bearing and steel producers in Mexico. We used a simple average of the range obtained from actual producers of the subject merchandise in Mexico as the most reasonable rate, given that there was no public information available on this subject. We reduced this rate by an amount to reflect indirect labor because the surrogate labor rate included indirect labor.
- We used the statutory minimum of ten percent of the sum of material and fabrication costs for general expenses.
- We used the statutory minimum of eight percent of material and fabrication costs plus general expenses for profit.
- Consistent with our valuation of packing in the Final Results of Antidumping Duty Administrative Review: Tapered Roller Bearings and Parts Thereof, Finished and Unfinished, from the Republic of Hungary, 56 FR 41819 (August 23, 1991), and the Final Results of Antidumping Duty Administrative Review: Tapered Roller Bearings and Parts Thereof, Finished and Unfinished, from the Republic of Hungary, 58 FR 47861 (September 13, 1993), the value of packing was based on publicly available data contained in the public file of the investigation of Tapered Roller Bearings from Italy, 52 FR 24198 (June 29, 1987). These data have been placed on the record for this administrative review.

Currency Conversion

We made currency conversions in accordance with 19 CFR 353.60(a). Currency conversions were made at the rates certified by the Federal Reserve Bank.

Preliminary Results of the Review

As a result of our comparison of the United States price to foreign market value, we preliminarily determine that the following dumping margin exists:

Manufacturer/ exporter	Time period	Margin (percent)
Magyar Gordulocs-opagy Muvek	6/1/91–5/31/92	5.89

Parties to the proceeding may request disclosure within 5 days of the date of publication of this notice. Any interested party may request a hearing within 10 days of publication. Any hearing, if requested, will be held 44 days after the publication of this notice, or the first workday thereafter. Interested parties may submit case briefs within 30 days of the date of publication of this notice. Rebuttal briefs, which must be limited to issues raised in the case briefs, may be filed not later than 37 days after the date of publication. The Department will publish a notice of final results of this administrative review, which will include the results of its analysis of issues raised in any such comments.

The Department shall determine, and the Customs Service shall assess, antidumping duties on all appropriate entries. Individual differences between United States price and foreign market value may vary from the percentage stated above. The Department will issue appraisement instructions directly to the Customs Service.

Furthermore, in accordance with section 751(a)(1) of the Act, we will instruct the Customs Service to collect cash deposits for MGM and all other exporters of Hungarian TRBs, at the rate indicated above. This deposit rate will be effective upon publication of the final results of this administrative review for all shipments of the subject merchandise entered, or withdrawn from warehouse, for consumption on or after the publication date. This deposit rate, when imposed, shall remain in effect until publication of the final results of the next administrative review.

This notice also serves as a preliminary reminder to importers of their responsibility under 19 CFR 353.26 to file a certificate regarding the reimbursement of antidumping duties prior to liquidation of the relevant entries during this review period. Failure to comply with this requirement could result in the Secretary's presumption that reimbursement of antidumping duties occurred and the subsequent assessment of double antidumping duties.

This administrative review and notice are in accordance with section 751(a)(1) of the Tariff Act (19 U.S.C. 1675(a)(1)) and 19 CFR 353.22.

Dated: November 17, 1993.

Barbara R. Stafford

Acting Assistant Secretary for Import Administration.

[FR Doc. 93–28755 Filed 11–22–93; 8:45 am]

BILLING CODE 3510–DS–P

National Institute of Standards and Technology

OSE Implementors' Workshop (OIW); Notice of 1994 Meeting Dates

AGENCY: National Institute of Standards and Technology (NIST), Commerce.

ACTION: Notice.

SUMMARY: The NIST announces four (4) workshop sessions to reach implementor agreements on Open System Environments (OSE) computer standards.

DATES: The 1994 meeting dates for the workshops have been established and are as follows: March 14–18, 1994, June 13–17, 1994, September 12–16, 1994, December 12–16, 1994.

The meetings will be hosted by NIST and held at Gaithersburg, Maryland.

ADDRESSES: To register for the workshops, companies may contact: OSE Implementors Workshop Series, Attn: Brenda Gray, National Institute of Standards and Technology, Building 225, room B–266, Gaithersburg, MD 20899, Telephone: (301) 975–3664.

The registration request must name the company representative(s) and specify the business address and telephone number for each participant.

FOR FURTHER INFORMATION CONTACT: For technical questions contact, Albert T. Landberg (301) 975–2245.

SUPPLEMENTARY INFORMATION: The workshops are an ideal vehicle for identifying candidate specifications to satisfy user needs for an open system application environments and developing functional standards (profiles) to meet interoperability requirements. A registration fee will be charged for attending the workshops. Participants are expected to make their own travel arrangements and accommodations. NIST reserves the right to cancel any part of the workshops.

Dated: November 16, 1993.

Samuel Kramer,

Associate Director.

[FR Doc. 93–28664 Filed 11–22–93; 8:45 am]

BILLING CODE 3510–CN–M

National Oceanic and Atmospheric Administration

Endangered Species; Permits

AGENCY: National Marine Fisheries Service (NMFS), NOAA, Commerce.

ACTION: Receipt of Application for a Second Modification to Scientific Research permit No. 822 (P500B).

Notice is hereby given that the Fish Passage Center (FPC) has applied in due form for a second modification to scientific research Permit No. 822 to take listed species as authorized by the Endangered Species Act of 1973 (ESA) (16 U.S.C. 1531–1543) and the NMFS regulations governing listed fish and wildlife permits (50 CFR part 217–227).

Permit No. 822 was issued on march 15, 1993 (58 FR 16524) as authorized by the ESA. It authorizes FPC to take listed Snake River sockeye salmon (*Oncorhynchus nerka*), Snake River fall chinook salmon (*O. tshawytscha*), and Snake River spring/summer chinook salmon (*O. tshawytscha*) for scientific research purposes through December 31, 1997.

FPC is requesting authorization to add smolt monitoring activities at Lower Granite, Little Goose, Lower Monumental and McNary dams to Permit No. 822. These activities were previously authorized under Permit 828, issued to the U.S. Army Corps of Engineers, which expires December 31 1993. The FPC is also requesting authorization to add a new smolt monitoring trap on the Grande Ronde River and increase handling efforts at the Clearwater River and Snake River (Lewiston) traps.

Addition of the transportation sites, the Grande Ronde River trap, and increases in sampling at the Snake River and Clearwater traps would increase the total numbers of listed fish authorized to be handled under Permit 822 from 12,410 to 52,410 juvenile Snake River spring/summer chinook salmon, from 216 to 24,316 juvenile Snake River fall chinook salmon, and from 10 to 130 juvenile Snake River sockeye salmon.

FPC is also requesting authorization to passive integrated transponder (PIT) tag subsets of the fish that would be handled at Lower Granite dam, the Snake River trap, which would increase the number of listed fish authorized to be PIT tagged under Permit 822 from 5,000 to 10,800 Snake River spring/summer chinook salmon and from 0 to 600 Snake River fall chinook salmon.

As a result of all of the above activities, FPC expects mortalities of listed fish that would be authorized under Permit 822 to increase from 125 to 535 Snake River spring/summer chinook salmon, from 6 to 566 Snake River fall chinook salmon, and from 1 to 13 Snake River sockeye salmon.

Written data or views, or requests for a public hearing on this modification request should be submitted to the Director, Office of Protected Resources, National Marine Fisheries Service, 1315 East-West Hwy., room 13229, Silver Spring, MD 20910, within 30 days of the publication of this notice. Those individuals requesting a hearing should set forth the specific reasons why a hearing on this particular request would be appropriate. The holding of such hearing is at the discretion of the Assistant Administrator for Fisheries. All statements and opinions contained in this request summary are those of the Applicant and do not necessarily reflect the views of NMFS.

Documents submitted in connection with the above request are available for review by interested persons in the following offices by appointment:

Office of Protected Resources, National Marine Fisheries Service, 1315 East-West Hwy., room 13229, Silver Spring, MD 20910 (301–713–2322); and

Environmental and Technical Services Division, National Marine Fisheries Service, 911 North East 11th Ave., Room 620, Portland, OR 97232 (503–230–5400).

Dated: November 15, 1993.

William W. Fox, Jr., Phd.

Director, Office of Protected Resources.

[FR Doc. 93–28642 Filed 11–22–93; 8:45 am]

BILLING CODE 3510–22–M

DEPARTMENT OF DEFENSE

Office of The Secretary

DoD Government-Industry Technical Data Committee

AGENCY: Office of the Under Secretary of Defense (Acquisition).

ACTION: Notice.

SUMMARY: Pursuant to Section 807 of Public Law 102–120, the National Defense Authorization Act for Fiscal Years 1992 and 1993, a Government-Industry Technical Data Committee has been formed. The committee will make recommendations to the Secretary of Defense for the final regulations required by subsection (a) of 10 U.S.C. 2320 "Rights in Technical Data."

The next committee meetings are scheduled for December 8 and 9, 1993, from 9:30 a.m. to 4 p.m. at The Russell Baker Conference Room, room 1000, 815 Connecticut Ave., NW., Washington, DC 20006–4078. These meetings will be open to the public. For more information, please contact the Committee Executive Secretary, Angelena Moy at (703) 693–5639.

Dated: November 17, 1993.

Patricia L. Toppings,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 93–28649 Filed 11–22–93; 8:45 am]

BILLING CODE 5000–04–M

Department of the Air Force

Privacy Act of 1974; Deletion and Amendment of Systems of Records

AGENCY: Department of the Air Force, DOD.

ACTION: Deletion and amendment of systems of records.

SUMMARY: The Department of the Air Force proposes to delete one and amend 24 systems of records notices to its inventory of systems of records notices subject to the Privacy Act of 1974 (5 U.S.C. 552a), as amended.

DATES: The deletion will be effective November 23, 1993.

The amendments will be effective on December 23, 1993, unless comments are received that would result in a contrary determination.

ADDRESSES: Send comments to the Assistant Air Force Access Programs Officer, SAF/AAIA, 1610 Air Force Pentagon, Washington, DC 20330–1610.

FOR FURTHER INFORMATION CONTACT: Mr. Jim Gibson at (703) 697–3491 or DSN 227–3491.

SUPPLEMENTARY INFORMATION: The complete inventory of Department of Air Force record system notices subject to the Privacy Act of 1974 (5 U.S.C. 552a), as amended, have been published in the **Federal Register** and are available from the address above.

Dated: November 17, 1993.

Patricia L. Toppings,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

DELETION

F050 AFCC D

SYSTEM NAME:

Student Record *(February 22, 1993, 58 FR 10391).*

Reason: System is no longer needed. There are no plans to reinstate this system in the future. Records maintained in this system will be destroyed nine years from date of discontinuance of the system.

AMENDMENTS
F011 AF A

SYSTEM NAME:

Locator, Registration and Postal Directory Files *(February 22, 1993, 58 FR 10289).*

CHANGES:

* * * * *

SYSTEM LOCATION:

Delete 'and specified'.

* * * * *

RETENTION AND DISPOSAL:

Delete entry and replace with 'Retained in office files until reassignment or separation, or when superseded or no longer needed for reference. Postal directory files are destroyed for one year after permanently assigned personnel depart, or three months after transient personnel depart. Records are destroyed by tearing into pieces, shredding, pulping, macerating or burning. Computer records are destroyed by erasing, deleting or overwriting.'

SYSTEM MANAGER(S) AND ADDRESS:

Change first sentence to read 'Director of Information Management, Office of the Administrative Assistant to the Secretary of the Air Force, 1680 Air Force Pentagon, Washington, DC 20330–1680.'

* * * * *

F011 AF A

SYSTEM NAME:

Locator, Registration and Postal Directory Files.

SYSTEM LOCATION:

Headquarters, United States Air Force; Air Force installations to include bases; units; offices and functions, and headquarters of unified commands for which Air Force is Executive Agent. Official mailing addresses are published as an appendix to the Air Force's compilation of record systems notices.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Air Force military and civilian personnel; Air Force Reserve and National Guard personnel; volunteer personnel; United States Armed Forces military and civilian personnel assigned to headquarters of unified and specified commands for which Air Force is Executive Agent, and contractor personnel. Dependents may also be included in this system.

CATEGORIES OF RECORDS IN THE SYSTEM:

Cards or listings may contain the individuals name, grade, military service identification number, Social Security Number, duty location, office telephone number, residence address and residence telephone number, and similar type personnel data determined to be necessary by local authority.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

10 U.S.C. 8013, Secretary of the Air Force: Powers and duties; delegation by, and E.O. 9397.

PURPOSE(S):

Used to locate or identify personnel assigned/attached to, tenanted on, or on temporary duty at the specific installation, office, base, unit, function, and/or organization in response to specific inquiries from authorized users for the conduct of business. Portions of the system are used for directory service and forwarding individual personal mail received by Air Force postal activities, and for assignment of individual mail boxes. Files may be used locally to support official and unofficial programs which require minimal locator information, membership or user listings.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSE OF SUCH USES:

In addition to those disclosures generally permitted under 5 U.S.C. 552a(b) of the Privacy Act, these records, or information contained therein, may specifically be disclosed outside the DOD as a routine use pursuant to 5 U.S.C. 552a(b)(3) as follows:

The 'Blanket Routine Uses' published at the beginning of the Air Force's compilation of systems of records notices apply to this system.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Maintained on paper records in card or form media in visible file binders/cabinets or card files, in computers and on computer output products.

RETRIEVABILITY:

Retrieved by name and/or Social Security Number.

SAFEGUARDS:

Records are accessed by person(s) responsible for servicing the record system in performance of their official duties and by authorized personnel who are properly screened and cleared for need-to-know. Records are stored in locked rooms and cabinets. Those in computer storage devices are protected by computer system software.

RETENTION AND DISPOSAL:

Retained in office files until reassignment or separation, or when superseded or no longer needed for reference. Postal directory files are destroyed for one year after permanently assigned personnel depart, or three months after transient personnel depart. Records are destroyed by tearing into pieces, shredding, pulping, macerating or burning. Computer records are destroyed by erasing, deleting or overwriting.

SYSTEM MANAGER(S) AND ADDRESS:

Director of Information Management, Office of the Administrative Assistant to the Secretary of the Air Force, 1680 Air Force Pentagon, Washington, DC 20330–1680.

Local system managers: Records Custodians at the installation, base, unit, organization, office or function to which the individual is assigned, attached, tenanted on, performing volunteer service at, or on temporary duty. Official mailing addresses are published as an appendix to the Air Force's compilation of record systems notices.

NOTIFICATION PROCEDURES:

Individuals seeking to determine whether this system of records contains information about themselves should address inquiries to or visit the local system manager. Official mailing addresses are published as an appendix to the Air Force's compilation of record systems notices.

RECORD ACCESS PROCEDURES:

Individuals seeking access to records about themselves contained in this system should address written requests to the local system manager. Official mailing addresses are published as an appendix to the Air Force's compilation of record systems notices.

CONTESTING RECORD PROCEDURES:

The Air Force rules for accessing records and for contesting contents and appealing initial agency determinations are published in Air Force Instruction 37–132; 32 CFR part 806b; or may be obtained from the system manager.

RECORD SOURCE CATEGORIES:

Information obtained from automated system interfaces; the individuals, or from personnel records.

EXEMPTIONS CLAIMED FOR THE SYSTEM:

None.

F030 MPC B

SYSTEM NAME:

Indebtedness, Nonsupport, Paternity *(February 22, 1993, 58 FR 10318).*

CHANGES:

* * * * *

SYSTEM LOCATION:

Delete entry and replace with 'Personal Programs Branch, Headquarters Air Force Military Personnel Center, 550 C Street W, Randolph Air Force Base, TX 78150–4717.'

* * * * *

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

Delete 'Air Force Regulation 35–18' and replace with 'Air Force Instruction 35–706, Personal Financial Responsibility.'

* * * * *

SAFEGUARDS:

Delete entry and replace with 'Records are accessed by person(s) responsible for servicing the record system in performance of their official duties and by authorized personnel who are properly screened and cleared for need-to-know. Records are stored in locked rooms and cabinets.'

* * * * *

SYSTEM MANAGER(S) AND ADDRESS:

Delete entry and replace with 'Chief, Personal Programs Branch, Records and Special Programs Division, Headquarters Air Force Military Personnel Center, 550 C Street W, Randolph Air Force Base, TX 78150–4714.'

NOTIFICATION PROCEDURE:

Delete entry and replace with 'Individuals seeking to determine whether this system of records contains information on themselves should address written inquiries to the Chief, Personal Programs Branch, Records and Special Programs Division, Headquarters Air Force Military Personnel Center, 550 C Street W, Randolph Air Force Base, TX 78150–4714.'

RECORD ACCESS PROCEDURES:

Delete entry and replace with 'Individuals seeking to access records about themselves contained in this system should address written requests to the Chief, Personal Programs Branch, Records and Special Programs Division, Headquarters Air Force Military Personnel Center, 550 C Street W, Randolph Air Force Base, TX 78150–4714.'

* * * * *

F030 MPC B

SYSTEM NAME:

Indebtedness, Nonsupport, Paternity.

SYSTEM LOCATION:

Personal Programs Branch, Headquarters Air Force Military Personnel Center, 550 C Street W, Randolph Air Force Base, TX 78150–4717.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Active duty military personnel who are the subject of complaints of indebtedness, nonsupport or inadequate support, or paternity allegations.

CATEGORIES OF RECORDS IN THE SYSTEM:

Correspondence relating to a complaint of indebtedness, nonsupport or inadequate support of dependents, or allegations of paternity with a report of the immediate commander's final action regarding same.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

10 U.S.C. 8013, Secretary of the Air Force: Powers and duties; delegation by; Air Force Instruction 35–706, Personal Financial Responsibility; and E.O. 9397.

PURPOSE(S):

Source of background information used for historical and statistical purposes.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

In addition to those disclosures generally permitted under 5 U.S.C. 552a(b) of the Privacy Act, these records or information contained therein may specifically be disclosed outside the DOD as a routine use pursuant to 5 U.S.C. 552a(b)(3) as follows:

The 'Blanket Routine Uses' published at the beginning of the Air Force's compilation of systems of records notices apply to this system.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Maintained in visible file binders/cabinets.

RETRIEVABILITY:

Retrieved by name.

SAFEGUARDS:

Records are accessed by person(s) responsible for servicing the record system in performance of their official duties and by authorized personnel who are properly screened and cleared for need-to-know. Records are stored in locked rooms and cabinets.

RETENTION AND DISPOSAL:

Retained for two years after end of year in which the case was closed, then destroyed by tearing into pieces, shredding, pulping, macerating, or burning.

SYSTEM MANAGER(S) AND ADDRESS:

Chief, Personal Programs Branch, Records and Special Programs Division, Headquarters Air Force Military Personnel Center, 550 C Street W, Randolph Air Force Base, TX 78150–4714.

NOTIFICATION PROCEDURE:

Individuals seeking to determine whether this system of records contains information on themselves should address written inquiries to the Chief, Personal Programs Branch, Records and Special Programs Division, Headquarters Air Force Military Personnel Center, 550 C Street W, Randolph Air Force Base, TX 78150–4714.

Individual should provide name, Social Security Number and date of birth.

RECORD ACCESS PROCEDURES:

Individuals seeking to access records about themselves contained in this system should address written requests to the Chief, Personal Programs Branch, Records and Special Programs Division, Headquarters Air Force Military Personnel Center, 550 C Street W, Randolph Air Force Base, TX 78150–4714.

Individual should provide name, Social Security Number and date of birth.

CONTESTING RECORD PROCEDURES:

The Air Force rules for accessing records and for contesting contents and appealing initial agency determinations are published in Air Force Instruction 37–132; 32 CFR part 806b; or may be obtained from the system manager.

RECORD SOURCE CATEGORIES:

Individuals, private concerns, and government agencies with interests pursuant to subject records.

EXEMPTIONS CLAIMED FOR THE SYSTEM:

None.

F035 AF A

SYSTEM NAME:

Officer Quality Force Management Records *(February 22, 1993, 58 FR 10320).*

CHANGES:

* * * * *

SYSTEM LOCATION:

Delete entry and replace with 'Headquarters United States Strategic Command, 901 SAC Boulevard, Suite

1F7, Offutt Air Force Base, NE 68113–1010.

Air Force Command, Control, Communications and Computer Agency, 203 W. Losey Street, Suite 1020, Scott Air Force Base, IL 62225–5219.'

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Delete entry and replace with 'Air Force active duty officers assigned or attached to Headquarters United States Strategic Command or Air Force Command, Control, Communications and Computer Agency, whose performance, conduct, or alleged misconduct may or has resulted in initiation of administrative action(s).'

* * * * *

PURPOSE(S):

Delete 'HQ USSTRATCOM' and 'HQ AFCC' and insert 'Headquarters United States Strategic Command' and 'Air Force Command, Control, Communications and Computer Agency' respectively.

* * * * *

SYSTEM MANAGER(S) AND ADDRESS:

Delete entry and replace with 'Chief, Personnel Programs Division, Directorate of Manpower and Personnel, Headquarters United States Strategic Command, 901 SAC Boulevard, Suite 1F7, Offutt Air Force Base, NE 68113–1010.

Chief, Personnel Programs Branch, Directorate of Resources, Air Force Command, Control, Communications and Computer Agency, 203 W. Losey Street, Suite 1020, Scott Air Force Base, IL 62225–5219.'

NOTIFICATION PROCEDURE:

Delete entry and replace with 'Individuals seeking to determine whether this system of records contains information on themselves should address written inquiries to the Chief, Personnel Programs Division, Directorate of Manpower and Personnel, Headquarters United States Strategic Command, 901 SAC Boulevard, Suite 1F7, Offutt Air Force Base, NE 68113–1010; or to the Chief, Personnel Programs Branch, Directorate of Resources, Air Force Command, Control, Communications and Computer Agency, 203 W. Losey Street, Suite 1020, Scott Air Force Base, IL 62225–5219.

Full name, military status, grade and Social Security Number are required to determine if the system contains records on an individual.

Visitors must provide proof of identity such as a military identification card, valid drivers license, or some item of information which can be verified from the records.'

RECORD ACCESS PROCEDURES:

Delete entry and replace with 'Individuals seeking to access records about themselves contained in this system should address written requests to the Chief, Personnel Programs Division, Directorate of Manpower and Personnel, Headquarters United States Strategic Command, 901 SAC Boulevard, Suite 1F7, Offutt Air Force Base, NE 68113–1010; or to the Chief, Personnel Programs Branch, Directorate of Resources, Air Force Command, Control, Communications and Computer Agency, 203 W. Losey Street, Suite 1020, Scott Air Force Base, IL 62225–5219.

Full name, military status, grade and Social Security Number are required to access records.

Visitors must provide proof of identity such as a military ID card, valid drivers license, or some item of information which can be verified from the records.'

* * * * *

RECORD SOURCE CATEGORIES:

Delete entry and replace with 'Information is obtained from the individual concerned; member's commander; Chief, Personnel Programs Division, Directorate of Manpower and Personnel, Headquarters United States Strategic Command, and Chief, Personnel Programs Branch, Directorate of Resources, Air Force Command, Control, Communications and Computer Agency.'

* * * * *

F035 AF A

SYSTEM NAME:

Officer Quality Force Management Records.

SYSTEM LOCATION:

Headquarters United States Strategic Command, 901 SAC Boulevard, Suite 1F7, Offutt Air Force Base, NE 68113–1010.

Air Force Command, Control, Communications and Computer Agency, 203 W. Losey Street, Suite 1020, Scott Air Force Base, IL 62225–5219.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Air Force active duty officers assigned or attached to Headquarters United States Strategic Command or Air Force Command, Control, Communications and Computer Agency, whose performance, conduct, or alleged misconduct may or has resulted in initiation of administrative action(s).

CATEGORIES OF RECORDS IN THE SYSTEM:

Information relating to substandard performance, unacceptable conduct or unfitness, and status and dates of pending or completed administrative actions.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

10 U.S.C. 8013, Secretary of the Air Force: Powers and duties; delegation by; 8074, Commands; territorial organization, and E.O. 9397.

PURPOSE(S):

To provide information to Commander in Chief, Headquarters United States Strategic Command; Deputy Chief of Staff for Personnel, Air Force Command, Control, Communications and Computer Agency; and staff members as appropriate who make decisions on officers' qualifications for continuation on active duty, or further consideration for promotion.

Used to evaluate and monitor status of actions on subjects.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSE OF SUCH USES:

In addition to those disclosures generally permitted under 5 U.S.C. 552a(b) of the Privacy Act, these records, or information contained therein, may specifically be disclosed outside the DOD as a routine use pursuant to 5 U.S.C. 552a(b)(3) as follows:

The 'Blanket Routine Uses' published at the beginning of the Air Force's compilation of systems of records notices apply to this system.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Maintained in computers and on computer output products.

RETRIEVABILITY:

Retrieved by name or Social Security Number.

SAFEGUARDS:

Records are accessed by the custodian of the record system and by persons responsible for servicing the records in performance of their official duties who are properly screened and cleared for need-to-know. Those in computer storage devices are protected by computer system software. Records and computer software are stored in locked cabinets and rooms in buildings protected by guards.

RETENTION AND DISPOSAL:

Retained until superseded, obsolete, or no longer needed for reference,

whichever is sooner. Files will be destroyed not later than 2 years from last entry. Records are destroyed by tearing into pieces, shredding, pulping, macerating or burning. Computer records are destroyed by erasing, deleting or overwriting.

SYSTEM MANAGER(S) AND ADDRESS:

Chief, Personnel Programs Division, Directorate of Manpower and Personnel, Headquarters United States Strategic Command, 901 SAC Boulevard, Suite 1F7, Offutt Air Force Base, NE 68113–1010.

Chief, Personnel Programs Branch, Directorate of Resources, Air Force Command, Control, Communications and Computer Agency, 203 W. Losey Street, Suite 1020, Scott Air Force Base, IL 62225–5219.

NOTIFICATION PROCEDURES:

Individuals seeking to determine whether this system of records contains information on themselves should address written inquiries to the Chief, Personnel Programs Division, Directorate of Manpower and Personnel, Headquarters United States Strategic Command, 901 SAC Boulevard, Suite 1F7, Offutt Air Force Base, NE 68113–1010; or to the Chief, Personnel Programs Branch, Directorate of Resources, Air Force Command, Control, Communications and Computer Agency, 203 W. Losey Street, Suite 1020, Scott Air Force Base, IL 62225–5219.

Full name, military status, grade and Social Security Number are required to determine if the system contains records on an individual.

Visitors must provide proof of identity such as a military identification card, valid drivers license, or some item of information which can be verified from the records.

RECORD ACCESS PROCEDURES:

Individuals seeking to access records about themselves contained in this system should address written requests to the Chief, Personnel Programs Division, Directorate of Manpower and Personnel, Headquarters United States Strategic Command, 901 SAC Boulevard, Suite 1F7, Offutt Air Force Base, NE 68113–1010; or to the Chief, Personnel Programs Branch, Directorate of Resources, Air Force Command, Control, Communications and Computer Agency, 203 W. Losey Street, Suite 1020, Scott Air Force Base, IL 62225–5219.

Full name, military status, grade and Social Security Number are required to access records.

Visitors must provide proof of identity such as a military ID card, valid drivers license, or some item of information which can be verified from the records.

CONTESTING RECORD PROCEDURES:

The Air Force rules for accessing records and for contesting contents and appealing initial agency determinations are published in Air Force Instruction 37–132; 32 CFR part 806b; or may be obtained from the system manager.

RECORD SOURCE CATEGORIES:

Information obtained from source documents; the individual concerned; member's commander; Chief, Personnel Programs Division, Directorate of Manpower and Personnel, Headquarters United States Strategic Command, and Chief, Personnel Programs Branch, Directorate of Resources, Air Force Command, Control, Communications and Computer Agency.

EXEMPTIONS CLAIMED FOR THE SYSTEM:

None.

F035 AF MP C

SYSTEM NAME:

Military Personnel Records System *(February 22, 1993, 58 FR 10323).*

CHANGES:

* * * * *

SYSTEM LOCATION:

Delete entry and replace with 'Headquarters United States Air Force, 1040 Air Force Pentagon, Washington, DC 20330–1040;

Headquarters Air Force Military Personnel Center, 550 C Street W, Randolph Air Force Base, TX 78150–4703;

Air Reserve Personnel Center, 6760 E. Irvington Place (6600), Denver, CO 80280–6600;

National Personnel Records Center, Military Personnel Records, 9700 Page Boulevard, St. Louis, MO 63132–2001.

Headquarters of major commands and separate operating agencies; consolidated base personnel offices; State Adjutant General Office of each respective state, District of Columbia and Commonwealth of Puerto Rico, and at Air Force Reserve and Air National Guard units. Official mailing addresses are published as an appendix to the Air Force's compilation of record system notices.'

* * * * *

CATEGORIES OF RECORDS IN THE SYSTEM:

Delete first portion of paragraph beginning with 'Officer Correspondence....' through 'MPerRGp at AFMPC...' and replace with 'Officer Correspondence and Miscellaneous Document Group (C and M) for active duty officers at Air Force Military Personnel Center (AFMPC); at Headquarters, United States Air Force (HQ USAF), Officer Selection Record (OSR) Group; at HQ USAF, General Officer Group; at HQ USAF AND HQ AFMPC Air Force Colonel's Group. Retired general officers Master Personnel Record Group (MPerRGp) at AFMPC; Officer Command Selection Record Group (OCSRGp) at the respective Air Force base of assignment/servicing Military Personnel Flight (MPF). Air Force active duty enlisted personnel MPerRGp and senior NCO selection folder at AFMPC; FRGp at respective servicing MPF; personnel in Temporary Disability Retired List (TDRL), Missing in Action (MIA), Prisoner of War (POW), Dropped From Rolls status MPerRGp at AFMPC.'

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

Delete 'Air Force Regulation 35–44' and replace with 'Air Force Instruction 36–2608.'

* * * * *

SYSTEM MANAGER(S) AND ADDRESS:

Delete entry and replace with 'Commander, Headquarters Air Force Military Personnel Center, 550 C Street W, Randolph Air Force Base, TX 78150–4703.'

NOTIFICATION PROCEDURE:

Delete the address in the first paragraph and replace with 'Commander, Headquarters Air Force Military Personnel Center, 550 C Street W, Randolph Air Force Base, TX 78150–4703.'

RECORD ACCESS PROCEDURES:

Delete the address in the first paragraph and replace with 'Commander, Headquarters Air Force Military Personnel Center, 550 C Street W, Randolph Air Force Base, TX 78150–4703.'

* * * * *

F035 AF MP C

SYSTEM NAME:

Military Personnel Records System.

SYSTEM LOCATION:

Headquarters United States Air Force, 1040 Air Force Pentagon, Washington, DC 20330–1040; Headquarters Air Force Military Personnel Center, 550 C Street W, Randolph Air Force Base, TX 78150–4703; Air Reserve Personnel Center, 6760 E. Irvington Place (6600), Denver, CO 80280–6600; National Personnel Records Center, Military Personnel Records, 9700 Page Boulevard, St. Louis, MO 63132–2001. Headquarters of

major commands and separate operating agencies; consolidated base personnel offices; State Adjutant General Office of each respective state, District of Columbia and Commonwealth of Puerto Rico, and at Air Force Reserve and Air National Guard units. Official mailing addresses are published as an appendix to the Air Force's compilation of record system notices.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Air Force active duty military, Air Force Reserve and Air National Guard personnel.

CATEGORIES OF RECORDS IN THE SYSTEM:

Officer Correspondence and Miscellaneous Document Group (C and M) for active duty officers at Air Force Military Personnel Center (AFMPC); at Headquarters, United States Air Force (HQ USAF), Officer Selection Record (OSR) Group; at HQ USAF, General Officer Group; at HQ USAF AND HQ AFMPC Air Force Colonel's Group. Retired general officers Master Personnel Record Group (MPerRGp) at AFMPC; Officer Command Selection Record Group (OCSRGp) at the respective Air Force base of assignment/ servicing Military Personnel Flight (MPF). Air Force active duty enlisted personnel MPerRGp and senior NCO selection folder at AFMPC; FRGp at respective servicing MPF; personnel in Temporary Disability Retired List (TDRL), Missing in Action (MIA), Prisoner of War (POW), Dropped From Rolls status MPerRGp at AFMPC; Reserve Officers MPerRGp at Air Reserve Personnel Center (ARPC); OCSR at the respective Air Force major command when applicable, FRGp at the respective unit of assignment or servicing CBPO or Consolidated Reserve Personnel Office (CRPO); Reserve airmen MPerRGp at ARPC and FRGp at the respective unit of assignment or servicing CBPO/CRPO; Air National Guard (ANGUS) officers MPerRGp at ARPC, OCSR at the respective State Adjutant General Office, and FRGp at the respective unit of assignment; ANGUS airmen MPerRGp at the respective State Adjutant General Office and FRGp at the respective unit of assignment; Retired and discharged Air Force military personnel MPerRGp at National Personnel Records Center and Air Force Academy cadets MPerRGp at unit of assignment CBPO. System contains substantiating documentation such as forms, certificates, administrative orders and correspondence pertaining to appointment as a commissioned officer, warrant officer, Regular AF, AF Reserve or ANGUS, enlistment/reenlistment/ extension of enlistment, assignment, Permanent Change of Station, Temporary Duty (TDY), promotion and demotion; identification card requests; casualty; duty status changes; Absent Without Leave/MIA/POW/Missing/ Deserter; military test administration/ results; service dates; separation; discharge/ retirement; security; training; Professional Military Education (PME); On-The-Job Training; Technical, General Military Training; commissioning; driver; academic education; performance/effectiveness reports; records corrections; formal/ informal medical or dental treatment/ examination; flying/rated status administration; extended active duty; emergency data; line of duty determinations; human/personnel reliability; career counseling; records transmittal; AF reserve administration; Air National Guard administration; board proceedings; personnel history statements; Department of Veterans Affairs compensations; disciplinary actions; record extracts; locator information; personal clothing/ equipment items; passport; classification; grade data; Career Reserve applications/cancellations; traffic safety; Unit Military Training; travel voucher for TDY to Republic of Vietnam; dependent data; professional achievements; Geneva Convention card; Federal insurance; travel and duty restrictions; Conscientious Objector status; decorations and awards; badges; Favorable Communications (colonels only); Inter-Service transfers; pay and allowances; combat duty; leave; photographs, and Personnel Data System products.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

10 U.S.C. 8013, Secretary of the Air Force: Powers and duties; delegation by; as implemented by Air Force Instruction 36–2608, and E.O. 9397.

PURPOSE(S):

Military personnel records are used at all levels of Air Force personnel management within the agency for actions/processes related to procurement, education and training, classification, assignment, career development, evaluation, promotion, compensation, sustentation, separation and retirement.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSE OF SUCH USES:

In addition to those disclosures generally permitted under 5 U.S.C. 552a(b) of the Privacy Act, these records or information contained therein may specifically be disclosed outside the DOD as a routine use pursuant to 5 U.S.C. 552a(b)(3) as follows:

Records may be disclosed to the Department of Veterans Affairs for research, processing and adjudication of claims, and providing medical care.

To dependents and survivors for determination of eligibility for identification card privileges.

To the Civilian Health and Medical Program of the Uniformed Services (CHAMPUS) for determination of eligibility and benefits.

To local Immigration/Naturalization Office for accountability and audit purposes.

To State Unemployment Compensation offices for verification of military service related information for unemployment compensation claims; Respective local state government offices for verification of Vietnam 'State Bonus' eligibility.

To the Office of Personnel Management for verification of military service for benefits, leave, or Reduction in Force purposes, and to establish Civil Service employee tenure and leave accrual rate.

To the Social Security Administration to substantiate applicant's credit for social security compensation; Local state office for verification of military service relative to the Soldiers and Sailors Civil Relief Act. Information as to name, rank, Social Security Number, salary, present and past duty assignment, future assignments that have been finalized, and office phone number may be provided to military financial institutions who provide services to DOD personnel. For personnel separated, discharged or retired from the Air Force, information as to last known address may be provided to the military financial institutions upon certification by a financial institution officer that the facility has a dishonored check or defaulted loan.

To the Selective Service Agencies for computation of service obligation.

To the American National Red Cross for emergency assistance to military members, dependents, relatives or other persons if conditions are compelling.

To the Department of Labor for claims of civilian employees formerly in military service, verification of service-related information for unemployment compensation claims, investigations of possible violations of labor laws and for pre-employment investigations.

To the National Research Council for medical research purposes.

To the U.S. Soldiers' and Airman's Home to determine eligibility.

In addition to those disclosures generally permitted under 5 U.S.C. 552a(b) of the Privacy Act, these records, or information contained therein, may specifically be disclosed outside the DOD as a routine use pursuant to 5 U.S.C. 552a(b)(3) as follows:

The 'Blanket Routine Uses' published at the beginning of the Air Force's compilation of systems of records notices apply to this system.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Maintained in visible file folders/ binders, cabinets and on computer and computer output products.

RETRIEVABILITY:

Information in the system is retrieved by last name, first name, middle initial and Social Security Number.

Records stored at National Personnel Records Center are retrieved by registry number, last name, first name, middle initial and Social Security Number.

SAFEGUARDS:

Records are accessed by person(s) responsible for servicing the records system in performance of their official duties and by authorized personnel who are properly screened and cleared for need-to-know. Records stored in locked room, cabinets, and in computer storage devices protected by computer system software.

RETENTION AND DISPOSAL:

Those documents designated as temporary in the prescribing directive remain in the records until their obsolescence (superseded, member terminates status, or retires) when they are removed and provided to the individual data subject.

Those documents designated as permanent remain in the military personnel records system permanently and are retired with the master personnel record group.

SYSTEM MANAGER(S) AND ADDRESS:

Commander, Headquarters Air Force Military Personnel Center, 550 C Street W, Randolph Air Force Base, TX 78150–4703.

NOTIFICATION PROCEDURE:

Individuals seeking to determine whether this system of records contains information on themselves should address written inquiries to the Commander, Headquarters Air Force Military Personnel Center, 550 C Street W, Randolph Air Force Base, TX 78150–4703.

Individuals may also appear in person at the responsible official's office or the respective repository for records for personnel in a particular category during normal duty hours any day except Saturday, Sunday or national and local holidays. The Saturday and Sunday exception does not apply to Reserve and National Guard units during periods of training. The system manager has the right to waive these requirements for personnel located in areas designated as Hostile Fire Pay areas. Official mailing addresses are published as an appendix to the Air Force's compilation of systems of records notices.

RECORD ACCESS PROCEDURES:

Individuals seeking to access records about themselves contained in this system should address written requests to the Commander, Headquarters Air Force Military Personnel Center, 550 C Street W, Randolph Air Force Base, TX 78150–4703.

Individuals may also appear in person at the responsible official's office or the respective repository for records for personnel in a particular category during normal duty hours any day except Saturday, Sunday or national and local holidays. The Saturday and Sunday exception does not apply to Reserve and National Guard units during periods of training. The system manager has the right to waive these requirements for personnel located in areas designated as Hostile Fire Pay areas. Official mailing addresses are published as an appendix to the Air Force's compilation of systems of records notices.

CONTESTING RECORD PROCEDURES:

The Air Force rules for accessing records and for contesting contents and appealing initial agency determinations are published in Air Force Instruction 37–132; 32 CFR part 806b; or may be obtained from the system manager.

RECORD SOURCE CATEGORIES:

Information is obtained from the subject of the file, supervisors, correspondence generated within the agency in the conduct of official business, educational institutions, and civil authorities.

EXEMPTION CLAIMED FOR THE SYSTEM:

None.

F035 AF MP L

SYSTEM NAME:

Unfavorable Information Files (UIF) *(February 22, 1993, 58 FR 10330).*

CHANGES:

* * * * *

SYSTEM LOCATION:

Delete entry and replace with 'Complete UIFs are maintained in the unit orderly room or the Military Personnel Flight (MPF) office. A copy of the UIF summary sheet is maintained at: Individual's unit of assignment; geographically separated units not collocated with a servicing MPF. For officers only at major command level; for colonel, colonel select, and general officers at Headquarters Air Force level; and the gaining unit for individuals selected for reassignment. Official mailing addresses are published as an appendix to the Air Force compilation of record system notices.'

* * * * *

CATEGORIES OF RECORDS IN THE SYSTEM:

Add to end of entry 'and drug/alcohol abuse correspondence.'

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

Delete 'Air Force Regulation 35–32' and insert 'Air Force Instruction 36–2907, The Air Force Unfavorable Information File Program.'

* * * * *

SYSTEM MANAGER(S) AND ADDRESS:

Delete entry and replace with 'Assistant Deputy Chief of Staff for Personnel, Headquarters Air Force Military Personnel Center, 550 C Street W, Randolph Air Force Base, TX 78150–4703.'

NOTIFICATION PROCEDURE:

Delete entry and replace with 'Personnel for whom optional UIFs exist are routinely notified of the existence of a file. In all cases personnel have had the opportunity and are authorized to rebut the correspondence in the file. Individuals seeking to determine whether this system of records contains information about themselves should address written inquiries to the servicing military personnel flight or unit orderly room. Official mailing addresses are published as an appendix to the Air Force's compilation of record system notices.'

RECORD ACCESS PROCEDURES:

Delete entry and replace with 'Individuals seeking access to records about themselves contained in this system should address written inquiries to the servicing military personnel flight or unit orderly room. Official mailing addresses are published as an appendix to the Air Force's compilation of record system notices.'

* * * * *

F035 AF MP L

SYSTEM NAME:

Unfavorable Information Files (UIF).

SYSTEM LOCATION:

Complete UIFs are maintained in the unit orderly room or the Military Personnel Flight (MPF) office. A copy of the UIF summary sheet is maintained at: Individual's unit of assignment; geographically separated units not collocated with a servicing MPF. For officers only at major command level; for colonel, colonel select, and general officers at Headquarters Air Force level; and the gaining unit for individuals selected for reassignment. Official mailing addresses are published as an appendix to the Air Force compilation of record system notices.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Active duty military personnel who are the subject of an UIF.

CATEGORIES OF RECORDS IN THE SYSTEM:

Derogatory correspondence determined as mandatory for file or as appropriate for file by an individual's commander. Examples include written admonitions or reprimands; court-martial orders; letters of indebtedness, or control roster correspondence and drug/alcohol abuse correspondence.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

10 U.S.C. 8013, Secretary of the Air Force: Powers and duties; delegation by; as implemented by Air Force Instruction 36–2907, The Air Force Unfavorable Information File Program.

PURPOSE(S):

Reviewed by commanders and personnel officials to assure appropriate assignment, promotion and reenlistment considerations prior to effecting such actions. UIFs also provide information necessary to support administrative separation when further rehabilitation efforts would not be considered effective.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSE OF SUCH USES:

In addition to those disclosures generally permitted under 5 U.S.C. 552a(b) of the Privacy Act, these records, or information contained therein, may specifically be disclosed outside the DOD as a routine use pursuant to 5 U.S.C. 552a(b)(3) as follows:

The 'Blanket Routine Uses' published at the beginning of the Air Force's compilation of systems of records notices apply to this system.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Maintained in visible file binders/ cabinets and in computers and on computer output products.

RETRIEVABILITY:

Retrieved by name.

SAFEGUARDS:

Records are accessed by custodian of the record system and by person(s) responsible for servicing the record system in performance of their official duties who are properly screened and cleared for need-to-know. Records are stored in locked cabinets or rooms. Computer records are protected by computer software.

RETENTION AND DISPOSAL:

UIFs are maintained for one year from the effective date of the most recent correspondence, except when the file contains documentation pertaining to Articles 15, Court-Martial or certain civil court convictions, in which case the retention period is two years from the date of that correspondence. Files are automatically destroyed upon separation or retirement, and on an individual basis when the individual's commander so determines. Destroy by tearing into pieces, shredding, pulping, macerating, or burning. Computer records are destroyed by degaussing or overwriting.

SYSTEM MANAGER(S) AND ADDRESS:

Assistant Deputy Chief of Staff for Personnel, Headquarters Air Force Military Personnel Center, 550 C Street W, Randolph Air Force Base, TX 78150–4703.

NOTIFICATION PROCEDURE:

Personnel for whom optional UIFs exist are routinely notified of the existence of a file. In all cases personnel have had the opportunity and are authorized to rebut the correspondence in the file. Individuals seeking to determine whether this system of records contains information about themselves should address written inquiries to the servicing military personnel flight or unit orderly room. Official mailing addresses are published as an appendix to the Air Force's compilation of record system notices.

RECORD ACCESS PROCEDURES:

Individuals seeking access to records about themselves contained in this system should address written inquiries to the servicing military personnel flight or unit orderly room. Official mailing addresses are published as an appendix to the Air Force's compilation of record system notices.

CONTESTING RECORD PROCEDURES:

The Air Force rules for accessing records and for contesting contents and appealing initial agency determinations are published in Air Force Instruction 37–132; 32 CFR part 806b; or may be obtained from the system manager.

RECORD SOURCE CATEGORIES:

Supervisory reports or censures and documented records of poor performance or conduct.

EXEMPTIONS CLAIMED FOR THE SYSTEM:

None.

F035 AF MP N

SYSTEM NAME:

Individual Weight Management and Physical Fitness File *(February 22, 1993, 58 FR 10332).*

CHANGES:

* * * * *

SYSTEM NAME:

Change system name to 'Individual Weight Management File.'

* * * * *

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Delete entry and replace with 'Air Force active duty military personnel; Air National Guard (ANG) and Air Force Reserve personnel who are enrolled in the Weight Management Control Program.'

CATEGORIES OF RECORDS IN THE SYSTEM:

Delete entry and replace with 'File contains individual weight management record; AF Form 108 informing individual of weight management program status, scheduled medical evaluations, and pertinent medical status.'

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

Delete entry and replace with '10 U.S.C. 8013, Secretary of the Air Force; Powers and duties, delegation by; as implemented by Air Force Instruction 36–2905, Air Force Weight Program.'

PURPOSE(S):

Delete entry and replace with 'The files keep the individual informed of weight/body fat loss in attaining body fat standards, provides history of weight/body fat loss and counseling, provides an input for medical determinations.'

* * * * *

RETENTION AND DISPOSAL:

Delete entry and replace with 'When a person achieves the prescribed weight

standards or desired fitness level, file is retained for one year from date of removal from the Weight Management Program and destroyed by unit; or destroyed upon retirement or separation by unit, whichever is earlier; or upon successful completion of probation and rehabilitation under Air Force Instruction 36–3208.

Records are destroyed by tearing into pieces, shredding, pulping, macerating or burning. Computer records are destroyed by erasing, deleting or overwriting.'

SYSTEM MANAGER(S) AND ADDRESS:

Delete entry and replace with 'Deputy Chief of Staff for Personnel, Headquarters Air Force Military Personnel Center, 550 C Street W, Randolph Air Force Base, TX 78150–4703.'

NOTIFICATION PROCEDURE:

Delete entry and replace with 'Individuals seeking to determine whether this system of records contains information on themselves should address written inquiries to the Commander at the unit of assignment or attachment.

Include full name, grade, and Social Security Number. Personal visits require proof of identity with an Armed Forces Identification Card.'

RECORD ACCESS PROCEDURES:

Delete entry and replace with 'Individuals seeking access to records about themselves contained in this system should address written requests to the Commander at the unit of assignment or attachment.

Include full name, grade, and Social Security Number. Personal visits require proof of identity with an Armed Forces Identification Card.'

* * * * *

F035 AF MP N

SYSTEM NAME:

Individual Weight Management File.

SYSTEM LOCATION:

Air Force unit of assignment or attachment and servicing medical facility. Official mailing addresses are published as an appendix to the Air Force's compilation of systems of records notices.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Air Force active duty military personnel; Air National Guard (ANG) and Air Force Reserve personnel who are enrolled in the Weight Management Control Program.

CATEGORIES OF RECORDS IN THE SYSTEM:

File contains individual weight management record; AF Form 108 informing individual of weight management program status, scheduled medical evaluations, and pertinent medical status.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

10 U.S.C. 8013, Secretary of the Air Force; Powers and duties, delegation by; as implemented by Air Force Instruction 36–2905, Air Force Weight Program; and E.O. 9397.

PURPOSE(S):

The files keep the individual informed of weight/body fat loss in attaining body fat standards, provides history of weight/body fat loss and counseling, provides an input for medical determinations.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

In addition to those disclosures generally permitted under 5 U.S.C. 552a(b) of the Privacy Act, these records, or information contained therein, may specifically be disclosed outside the DOD as a routine use pursuant to 5 U.S.C. 552a(b)(3) as follows:

The 'Blanket Routine Uses' published at the beginning of the Air Force's compilation of systems of records notices apply to this system.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Maintained in file folders and on computer and computer output products.

RETRIEVABILITY:

Retrieved by name, Social Security Number and grade.

SAFEGUARDS:

Records are accessed by custodian of the records system and by person(s) responsible for servicing the records system in performance of their official duties who are properly screened and cleared for need-to-know. Records are controlled by personnel screening.

RETENTION AND DISPOSAL:

When a person achieves the prescribed weight standards or desired fitness level, file is retained for one year from date of removal from the Weight Management Program and destroyed by unit; or destroyed upon retirement or separation by unit, whichever is earlier; or upon successful completion of probation and rehabilitation under Air Force Instruction 36–3208.

Records are destroyed by tearing into pieces, shredding, pulping, macerating or burning. Computer records are destroyed by erasing, deleting or overwriting.

SYSTEM MANAGER(S) AND ADDRESS:

Deputy Chief of Staff for Personnel, Headquarters Air Force Military Personnel Center, 550 C Street W, Randolph Air Force Base, TX 78150–4703.

NOTIFICATION PROCEDURE:

Individuals seeking to determine whether this system of records contains information on themselves should address written inquiries to the Commander at the unit of assignment or attachment. Include full name, grade, and Social Security Number.

Personal visits require proof of identity with an Armed Forces Identification Card.

RECORD ACCESS PROCEDURES:

Individuals seeking access to records about themselves contained in this system should address written requests to the Commander at the unit of assignment or attachment.

Include full name, grade, and Social Security Number. Personal visits require proof of identity with an Armed Forces Identification Card.

CONTESTING RECORD PROCEDURES:

The Air Force rules for accessing records and for contesting contents and appealing initial agency determinations are published in Air Force Instruction 37–132; 32 CFR part 806b; or may be obtained from the system manager.

RECORD SOURCE CATEGORIES:

Individuals to whom the record pertains.

EXEMPTIONS CLAIMED FOR THE SYSTEM:

None.

F035 MPC C

SYSTEM NAME:

Chaplain Applicant Processing Folder *(February 22, 1993, 58 FR 10357).*

CHANGES:

SYSTEM IDENTIFIER:

Change system identifier to 'F035 HC D.'

* * * * *

SYSTEM LOCATION:

Delete entry and replace with 'Office of the Chief of Chaplains, Headquarters United States Air Force, 172 Luke Avenue, 3rd Floor, Washington, DC 20330–5113.'

* * * * *

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

Delete 'Air Force Regulation 36–15' and insert 'Air Force Instruction 36–2005, Appointment in Commissioned Grades and Designation and Assignment in Professional Categories Reserve of the Air Force and United States Air Force (Temporary).'

* * * * *

SAFEGUARDS:

Delete entry and replace with 'Records are accessed by person(s) responsible for servicing the record system in performance of their official duties and by authorized personnel who are properly screened and cleared for need-to-know. Records are stored in locked rooms and cabinets.'

* * * * *

SYSTEM MANAGER(S) AND ADDRESS:

Delete entry and replace with 'Chief of Chaplains, Headquarters United States Air Force, 172 Luke Avenue, 3rd Floor, Washington, DC 20330–5113.'

NOTIFICATION PROCEDURE:

Delete address and replace with 'Chief of Chaplains, Headquarters United States Air Force, 172 Luke Avenue, 3rd Floor, Washington, DC 20330–5113.'

RECORD ACCESS PROCEDURES:

Delete address and replace with 'Chief of Chaplains, Headquarters United States Air Force, 172 Luke Avenue, 3rd Floor, Washington, DC 20330–5113.'

* * * * *

F035 HC D

SYSTEM NAME:

Chaplain Applicant Processing Folder.

SYSTEM LOCATION:

Office of the Chief of Chaplains, Headquarters United States Air Force, 172 Luke Avenue, 3rd Floor, Washington, DC 20330–5113.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Chaplaincy applicants and Reserve Chaplains applying for active duty.

CATEGORIES OF RECORDS IN THE SYSTEM:

Forms used by the Air Force Manpower and Personnel Center (AFMPC) Command Chaplains Office in processing chaplains to active duty including: Application for Appointment as Reserve of the Air Force; Application for Extended Active Duty with the United States Air Force; United States Air Force (USAF) Drug Abuse Certificate; Statement of Personal History; National Agency Check Request; Report of Medical Examination; Report of Medical History; Fingerprint Card; Checklist for Chaplain Appointment; Ecclesiastical Endorsement; Certificate of Continuance of Ecclesiastical Endorsement; Certificate of Seminary Graduation and Ordination; Official Transcripts of College Education; Personal correspondence between resource manager and applicant regarding status of his application.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

10 U.S.C. 8067, Designation: Officers to perform certain professional . functions, and 8293, Commissioned officers; chaplains: Original appointment; examination; as implemented by Air Force Instruction 36–2005, Appointment in Commissioned Grades and Designation and Assignment in Professional Categories Reserve of the Air Force and United States Air Force (Temporary).

PURPOSE(S):

The documents maintained in these transitory folders are used by the resource manager in processing chaplain applicants to active duty.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

In addition to those disclosures generally permitted under 5 U.S.C. 552a(b) of the Privacy Act, these records, or information contained therein, may specifically be disclosed outside the DOD as a routine use pursuant to 5 U.S.C. 552a(b)(3) as follows:

The 'Blanket Routine Uses' published at the beginning of the Air Force's compilation of systems of records notices apply to this system.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Maintained in visible file binders/ cabinets.

RETRIEVABILITY:

Retrieved by name.

SAFEGUARDS:

Records are accessed by person(s) responsible for servicing the record system in performance of their official duties and by authorized personnel who are properly screened and cleared for need-to-know. Records are stored in locked rooms and cabinets.

RETENTION AND DISPOSAL:

Once applicant is accessed, forms are entered into the Master Personnel Records Group. If applicant does not qualify for appointment, file is destroyed after one year.

SYSTEM MANAGER(S) AND ADDRESS:

Chief of Chaplains, Headquarters United States Air Force, 172 Luke Avenue, 3rd Floor, Washington, DC 20330–5113.

NOTIFICATION PROCEDURE:

Individuals seeking to determine whether this system of records contains information on themselves should address written inquiries to the Chief of Chaplains, Headquarters United States Air Force, 172 Luke Avenue, 3rd Floor, Washington, DC 20330–5113.

RECORD ACCESS PROCEDURES:

Individuals seeking to access records about themselves contained in this system should address written requests to the Chief of Chaplains, Headquarters United States Air Force, 172 Luke Avenue, 3rd Floor, Washington, DC 20330–5113.

CONTESTING RECORD PROCEDURES:

The Air Force rules for accessing records, and for contesting contents and appealing initial agency determinations are published in Air Force Regulation 12–35; 32 CFR part 806b; or may be obtained from the system manager.

RECORD SOURCE CATEGORIES:

Individual's application.

EXEMPTIONS CLAIMED FOR THE SYSTEM:

None.

F035 MPC D

SYSTEM NAME:

Correction of Military Record Card *(February 22, 1993, 58 FR 10357).*

CHANGES:

* * * * *

SYSTEM NAME:

Delete 'Card' and replace with 'System.'

SYSTEM LOCATION:

Delete entry and replace with 'Headquarters Air Force Military Personnel Center, 550 C Street W, Randolph Air Force Base, TX 78150–4703.'

* * * * *

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

Delete entry and replace with '10 U.S.C. Chapter 79 Correction of Military Records; as implemented by Air Force Instruction 36–2603, Air Force Board for the Correction of Military Records.'

* * * * *

RETENTION AND DISPOSAL:

Delete entry and replace with 'Maintained in computer system for five years. Computer records are destroyed by erasing, deleting or overwriting.'

SYSTEM MANAGER(S) AND ADDRESS:

Delete entry and replace with 'Assistant Deputy Chief of Staff for Personnel, Headquarters Air Force Military Personnel Center, 550 C Street W, Randolph Air Force Base, TX 78150–4703.'

NOTIFICATION PROCEDURE:

Delete address and replace with 'Assistant Deputy Chief of Staff for Personnel, Headquarters Air Force Military Personnel Center, 550 C Street W, Randolph Air Force Base, TX 78150–4703.'

RECORD ACCESS PROCEDURES:

Delete address and replace with 'Assistant Deputy Chief of Staff for Personnel, Headquarters Air Force Military Personnel Center, 550 C Street W, Randolph Air Force Base, TX 78150–4703.'

* * * * *

F035 MPC D

SYSTEM NAME:

Correction of Military Record System.

SYSTEM LOCATION:

Headquarters Air Force Military Personnel Center, 550 C Street W, Randolph Air Force Base, TX 78150–4703.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Active and retired or discharged officers and airmen. Next of kin of deceased officers and airmen.

CATEGORIES OF RECORDS IN THE SYSTEM:

Summary of application for correction of records request followed through to its final decision by the appropriate correction board.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

10 U.S.C. Chapter 79 Correction of Military Records; as implemented by Air Force Instruction 36–2603, Air Force Board for the Correction of Military Records; and E.O. 9397.

PURPOSE(S):

To monitor application by member and cocase by the appropriate correction board.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

In addition to those disclosures generally permitted under 5 U.S.C. 552a(b) of the Privacy Act, these records, or information contained therein, may specifically be disclosed outside the DOD as a routine use pursuant to 5 U.S.C. 552a(b)(3) as follows:

The 'Blanket Routine Uses' published at the beginning of the Air Force's compilation of systems of records notices apply to this system.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Maintained on computer magnetic tapes, disks, or computer paper printouts, or microfiche.

RETRIEVABILITY:

Retrieved by Social Security Number or Air Force Service Number.

SAFEGUARDS:

Records are accessed by custodian of the record system and by person(s) responsible for servicing the record system in performance of their official duties who are properly screened and cleared for need-to-know. Records are stored in locked cabinets or rooms and computer system software.

RETENTION AND DISPOSAL:

Maintained in computer system for five years. Computer records are destroyed by erasing, deleting or overwriting.

SYSTEM MANAGER(S) AND ADDRESS:

Assistant Deputy Chief of Staff for Personnel, Headquarters Air Force Military Personnel Center, 550 C Street W, Randolph Air Force Base, TX 78150–4703.

NOTIFICATION PROCEDURE:

Individuals seeking to determine whether this system of records contains information on themselves should address written inquiries to the Assistant Deputy Chief of Staff for Personnel, Headquarters Air Force Military Personnel Center, 550 C Street W, Randolph Air Force Base, TX 78150–4703.

RECORD ACCESS PROCEDURES:

Individuals seeking to access records about themselves contained in this system should address written requests to the Assistant Deputy Chief of Staff for Personnel, Headquarters Air Force Military Personnel Center, 550 C Street W, Randolph Air Force Base, TX 78150–4703.

CONTESTING RECORD PROCEDURES:

The Air Force rules for accessing records and for contesting contents and appealing initial agency determinations are published in Air Force Instruction 37–132; 32 CFR part 806b; or may be obtained from the system manager.

RECORD SOURCE CATEGORIES:

Member's application, Master Personnel Records.

EXEMPTIONS CLAIMED FOR THE SYSTEM:

None.

F035 MPC E

SYSTEM NAME:

Disability/Non-disability Retirements Records *(February 22, 1993, 58 FR 10358).*

CHANGES:

* * * * *

SYSTEM NAME:

Change system name to 'Disability Retirement Records.'

SYSTEM LOCATION:

Delete entry and replace with 'Headquarters Air Force Military Personnel Center, 550 C Street W, Randolph Air Force Base, TX 78150–4708.'

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Delete entry and replace with 'Officers and airmen on the Temporary Disability Retired List.'

CATEGORIES OF RECORDS IN THE SYSTEM:

Delete the last five words of the entry.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

Delete entry and replace with '10 U.S.C. Chapter 61, Retirement or Separation for Physical Disability; as implemented by Air Force Instruction 36–2902, Physical Evaluation for Retention, Retirement and Separation.'

* * * * *

STORAGE:

Delete 'and in microcomputers.'

RETRIEVABILITY:

Delete 'or Social Security Number.'

SAFEGUARDS:

Delete last sentence.

RETENTION AND DISPOSAL:

Delete entry and replace with 'Disability retain files are retained for 30 days after case is finalized; case files are retired to Master Personnel Records Group when disability retirement action has been completed.'

SYSTEM MANAGER(S) AND ADDRESS:

Delete entry and replace with 'Assistant Deputy Chief of Staff for Personnel, Headquarters Air Force

Military Personnel Center, 550 C Street W, Randolph Air Force Base, TX 78150–4703.'

NOTIFICATION PROCEDURE:

Delete address and replace with 'Assistant Deputy Chief of Staff for Personnel, Headquarters Air Force Military Personnel Center, 550 C Street W, Randolph Air Force Base, TX 78150–4703.'

RECORD ACCESS PROCEDURES:

Delete address and replace with 'Assistant Deputy Chief of Staff for Personnel, Headquarters Air Force Military Personnel Center, 550 C Street W, Randolph Air Force Base, TX 78150–4703.'

* * * * *

RECORD SOURCE CATEGORIES:

Delete entry and replace with 'Correspondence and forms generated in Retirements Branch, Headquarters Air Force Military Personnel Center (AFMPC); military hospitals; HQ USAF Surgeon General; HQ AFMPC Surgeon; consolidated base personnel offices; major air commands; by the members themselves, and by the general public on retirement-related matters.'

* * * * *

F035 MPC E

SYSTEM NAME:

Disability Retirement Records.

SYSTEM LOCATION:

Headquarters Air Force Military Personnel Center, 550 C Street W, Randolph Air Force Base, TX 78150–4708.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Officers and airmen on the Temporary Disability Retired List.

CATEGORIES OF RECORDS IN THE SYSTEM:

Copies of medical histories, Secretarial determinations, retirement forms, routine correspondence files, case files, disability retain folders.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

10 U.S.C. Chapter 61, Retirement or Separation for Physical Disability; as implemented by Air Force Instruction 36–2902, Physical Evaluation for Retention, Retirement and Separation.

PURPOSE(S):

To provide information on retirement cases and to allow appropriate case processing.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

In addition to those disclosures generally permitted under 5 U.S.C. 552a(b) of the Privacy Act, these records, or information contained therein, may specifically be disclosed outside the DOD as a routine use pursuant to 5 U.S.C. 552a(b)(3) as follows:

The 'Blanket Routine Uses' published at the beginning of the Air Force's compilation of systems of records notices apply to this system.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Maintained in visible file binders/cabinets.

RETRIEVABILITY:

Retrieved by name.

SAFEGUARDS:

Records are accessed by custodian of the record system and by person(s) responsible for servicing the record system in performance of their official duties who are properly screened and cleared for need-to-know. Stored in secure building.

RETENTION AND DISPOSAL:

Disability retain files are retained for 30 days after case is finalized; case files are retired to Master Personnel Records Group when disability retirement action has been completed.

SYSTEM MANAGER(S) AND ADDRESS:

Assistant Deputy Chief of Staff for Personnel, Headquarters Air Force Military Personnel Center, 550 C Street W, Randolph Air Force Base, TX 78150–4703.

NOTIFICATION PROCEDURE:

Individuals seeking to determine whether this system of records contains information on themselves should address written inquiries to the Assistant Deputy Chief of Staff for Personnel, Headquarters Air Force Military Personnel Center, 550 C Street W, Randolph Air Force Base, TX 78150–4703.

RECORD ACCESS PROCEDURES:

Individuals seeking to access records about themselves contained in this system should address written requests to the Assistant Deputy Chief of Staff for Personnel, Headquarters Air Force Military Personnel Center, 550 C Street W, Randolph Air Force Base, TX 78150–4703.

CONTESTING RECORD PROCEDURES:

The Air Force rules for accessing records and for contesting contents and appealing initial agency determinations are published in Air Force Instruction 37–132; 32 CFR part 806b; or may be obtained from the system manager.

RECORD SOURCE CATEGORIES:

Correspondence and forms generated in Retirements Branch, Headquarters Air Force Military Personnel Center (AFMPC); military hospitals; HQ USAF Surgeon General; HQ AFMPC Surgeon; consolidated base personnel offices; major air commands; by the members themselves, and by the general public on retirement-related matters.

EXEMPTIONS CLAIMED FOR THE SYSTEM:

None.

F035 MPC F

SYSTEM NAME:

Health Education Records *(February 22, 1993, 58 FR 10358).*

CHANGES:

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SYSTEM LOCATION:

Delete entry and replace with 'Headquarters Air Force Military Personnel Center, Chief, Medical Service Officer Utilization Division, 550 C Street W, Randolph Air Force Base, TX 78150–4703.'

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Delete entry and replace with 'All airmen and officers of the United States Air Force who have applied for training to Air Force Military Personnel Center/Medical Service Officer Utilization Division.'

CATEGORIES OF RECORDS IN THE SYSTEM:

Delete entry and replace with 'PHYSICIAN EDUCATION BRANCH:

Undergraduate Selection Folders: Application; Medical College Admission Test; Letter of acceptance to approved medial school; Dean's letter of recommendation; DD Form 398, Personal History Statement; Health Professions Scholarship Program (HPSP); Uniformed Services University of the Health Sciences service obligation contracts; Air Reserve Personnel Center order; Privacy Act Statement; Photo; HPSP selection notification letter; Physical exam; Separation order.

Graduate Medical Education Folders: Medical College Admission Test; final medical school transcript; Dean's letter from medical school; hospital agreement form; Privacy Act Statement; photo; application for training; AFMPC Form

131, Education Summary; Program Director's letter; other letters of recommendation; memos for record; Congressional inquiries; general correspondence; legal opinions for correction of military records; essay on career intention and professional goals; residency/fellowship resignation letters; select notification letter; Active Duty Service Commitment statement; redeferred statement of understanding.

MEDICAL SERVICE CORPS UTILIZATION AND EDUCATION BRANCH:

Air Force Institute of Technology Sponsored Graduate Education Folders: Transcripts; chronological listings of work experience (VITAE); letters of recommendation; graduate record examination results; Graduate Management Admission Test results; officer career briefs.

DENTAL UTILIZATION AND EDUCATION BRANCH:

Graduate Dental Education Folders: Application for sponsored training; graduate record examination results; essay on why program is desired; letters of recommendation; general correspondence with applicant; select/non-select/alternate letter; Dean's letter; Active Duty Service Commitment statement.'

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PURPOSE(S):

Delete entry and replace with 'Used by the Medical Service Officer Utilization Division/Branches and Medical Education Selection Boards in selecting individuals to attend undergraduate and graduate educational programs. Such programs include medical school, residencies and fellowship programs for physicians, graduate dental education and graduate education for Medical Service Corps officers. Another use of the system is to monitor the individual's progress in an educational program after selection until completion of program.'

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RETENTION AND DISPOSAL:

Delete entry and replace with 'Undergraduate and graduate medical education records are retained until the individual separates or retires from the Air Force. Air Force Institute of Technology (AFIT) selection folders are maintained until the end of the calendar year with the exception of transcripts which are returned to AFIT within 60 days of board completion. Dental graduate education folders are maintained while member is in program. Upon graduation, only transcripts, letters of recommendation, Graduate Record Examination results and Active Duty Service Commitment statements are maintained until member separates, retires or is promoted to colonel. When promoted to colonel, records are transferred to the Colonel's Group.'

SYSTEM MANAGER(S) AND ADDRESS:

Delete entry and replace with 'Chief, Medical Service Officer Utilization Division, Headquarters Air Force Military Personnel Center, 550 C Street W, Randolph Air Force Base, TX 78150–4703.'

NOTIFICATION PROCEDURE:

Delete address and replace with 'Chief, Medical Service Officer Utilization Division, Headquarters Air Force Military Personnel Center, 550 C Street W, Randolph Air Force Base, TX 78150–4703.'

RECORD ACCESS PROCEDURES:

Delete address and replace with 'Chief, Medical Service Officer Utilization Division, Headquarters Air Force Military Personnel Center, 550 C Street W, Randolph Air Force Base, TX 78150–4703.'

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F035 MPC F

SYSTEM NAME:

Health Education Records.

SYSTEM LOCATION:

Headquarters Air Force Military Personnel Center, Chief, Medical Service Officer Utilization Division, 550 C Street W, Randolph Air Force Base, TX 78150–4703.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

All airmen and officers of the United States Air Force who have applied for training to Air Force Military Personnel Center/Medical Service Officer Utilization Division.

CATEGORIES OF RECORDS IN THE SYSTEM:

PHYSICIAN EDUCATION BRANCH:

Undergraduate Selection Folders: Application; Medical College Admission Test; Letter of acceptance to approved medial school; Dean's letter of recommendation; DD Form 398, Personal History Statement; Health Professions Scholarship Program (HPSP); Uniformed Services University of the Health Sciences service obligation contracts; Air Reserve Personnel Center order; Privacy Act Statement; Photo; HPSP selection notification letter; Physical exam; Separation order.

Graduate Medical Education Folders: Medical College Admission Test; final medical school transcript; Dean's letter from medical school; hospital agreement form; Privacy Act Statement; photo; application for training; AFMPC Form 131, Education Summary; Program Director's letter; other letters of recommendation; memos for record; Congressional inquiries; general correspondence; legal opinions for correction of military records; essay on career intention and professional goals; residency/fellowship resignation letters; select notification letter; Active Duty Service Commitment statement; redeferred statement of understanding.

MEDICAL SERVICE CORPS UTILIZATION AND EDUCATION BRANCH:

Air Force Institute of Technology Sponsored Graduate Education Folders: Transcripts; chronological listings of work experience (VITAE); letters of recommendation; graduate record examination results; Graduate Management Admission Test results; officer career briefs.

Education With Industry Fellowship Application Folders: Military Facility Fellowship Application Folders; Professional Military Education Application Folders: VITAE; letters of recommendation; officer career briefs.

DENTAL UTILIZATION AND EDUCATION BRANCH:

Graduate Dental Education Folders: Application for sponsored training; graduate record examination results; essay on why program is desired; letters of recommendation; general correspondence with applicant; select/non-select/alternate letter; Dean's letter; Active Duty Service Commitment statement.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

10 U.S.C. 105, Armed Forces Health Professions Scholarship and 10 U.S.C. 9301, Members of Air Force: Detail as students, observers, and investigators at educational institutions, industrial plants, and hospitals.

PURPOSE(S):

Used by the Medical Service Officer Utilization Division/Branches and Medical Education Selection Boards in selecting individuals to attend undergraduate and graduate educational programs. Such programs include medical school, residencies and fellowship programs for physicians, graduate dental education and graduate education for Medical Service Corps officers. Another use of the system is to monitor the individual's progress in an educational program after selection until completion of program.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSE OF SUCH USES:

In addition to those disclosures generally permitted under 5 U.S.C. 552a(b) of the Privacy Act, these records, or information contained therein, may specifically be disclosed outside the DOD as a routine use pursuant to 5 U.S.C. 552a(b)(3) as follows:

The 'Blanket Routine Uses' published at the beginning of the Air Force's compilation of systems of records notices apply to this system.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Maintained in visible file binders/ cabinets.

RETRIEVABILITY:

Retrieved by name.

SAFEGUARDS:

Records are accessed by custodian of the record system and by person(s) responsible for servicing the record system in performance of their official duties who are properly screened and cleared for need-to-know. Records are stored in locked cabinets or rooms.

RETENTION AND DISPOSAL:

Undergraduate and graduate medical education records are retained until the individual separates or retires from the Air Force. Air Force Institute of Technology (AFIT) selection folders are maintained until the end of the calendar year with the exception of transcripts which are returned to AFIT within 60 days of board completion. Dental graduate education folders are maintained while member is in program. Upon graduation, only transcripts, letters of recommendation, Graduate Record Examination results and Active Duty Service Commitment statements are maintained until member separates, retires or is promoted to colonel. When promoted to colonel, records are transferred to the Colonel's Group.

SYSTEM MANAGER(S) AND ADDRESS:

Chief, Medical Service Officer Utilization Division, Headquarters Air Force Military Personnel Center, 550 C Street W, Randolph Air Force Base, TX 78150–4703.

NOTIFICATION PROCEDURE:

Individuals seeking to determine whether this system of records contains information on themselves should address written inquiries to the Chief, Medical Service Officer Utilization Division, Headquarters Air Force Military Personnel Center, 550 C Street W, Randolph Air Force Base, TX 78150–4703.

RECORD ACCESS PROCEDURES:

Individuals seeking to access records about themselves contained in this system should address written requests to the Chief, Medical Service Officer Utilization Division, Headquarters Air Force Military Personnel Center, 550 C Street W, Randolph Air Force Base, TX 78150–4703.

CONTESTING RECORD PROCEDURES:

The Air Force rules for accessing records and for contesting contents and appealing initial agency determinations are published in Air Force Instruction 37–132; 32 CFR part 806b; or may be obtained from the system manager.

RECORD SOURCE CATEGORIES:

Member's application, supervisor's evaluation, master personnel records (board use only), Career Brief (board use only), transcripts, test scores, Deans' letters of recommendation, Standard Form (SF) 88 and SF 93.

EXEMPTIONS CLAIMED FOR THE SYSTEM:

None.

F035 MPC G

SYSTEM NAME:

Medical Officer Personnel Utilization Records *(February 22, 1993, 58 FR 10359).*

CHANGES:

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SYSTEM LOCATION:

Delete entry and replace with 'Headquarters Air Force Military Personnel Center, Medical Service Officer Utilization Division, 550 C Street W, Randolph Air Force Base, TX 78150–4703.'

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AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

Delete entry and replace with '10 U.S.C. 8013, Secretary of the Air Force: Powers and duties; delegation by; as implemented by Air Force Instruction 36–2105, Officer Classification; Air Force Regulation 36–4, Special Pay for Medical Corps Officers; Air Force Instruction 36–2610, Appointment of Officers in the Regular Air Force; Air Force Instruction 36–2110, Continuation Pay for Dental Corps Officers; Air Force Regulation 36–20, Officer Assignments; Air Force Regulation 36–21, Selective Continuation Program; Air Force Instruction 36–2107, Active Duty Service Commitments (PA); and Air Force Instruction 36–2107, Specified Period of Time Contracts (SPTC) (PA).'

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SYSTEM MANAGER(S) AND ADDRESS:

Delete entry and replace with 'Deputy Director of Medical Service Officer Management, Headquarters Air Force Military Personnel Center, 550 C Street W, Randolph Air Force Base, TX 78150–4703.'

NOTIFICATION PROCEDURE:

Delete address and replace with 'Deputy Director of Medical Service Officer Management, Headquarters Air Force Military Personnel Center, 550 C Street W, Randolph Air Force Base, TX 78150–4703.'

RECORD ACCESS PROCEDURES:

Delete address and replace with 'Deputy Director of Medical Service Officer Management, Headquarters Air Force Military Personnel Center, 550 C Street W, Randolph Air Force Base, TX 78150–4703.'

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F035 MPC G

SYSTEM NAME:

Medical Officer Personnel Utilization Records.

SYSTEM LOCATION:

Headquarters Air Force Military Personnel Center, Medical Service Officer Utilization Division, 550 C Street W, Randolph Air Force Base, TX 78150–4703.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

All Air Force active duty medical service officers.

CATEGORIES OF RECORDS IN THE SYSTEM:

Personnel Utilization records containing: Career briefs; Print-outs; Letters from individuals; Letters from Utilization Branch to individuals Letters concerning medical service education and training; Copy of application for Indefinite Reserve Status; Copy of request to join spouse; Copy of Specified Period of Time Contract (SPTC) requests; Copy Air Force Manpower and Personnel Center (AFMPC) Form 8, Assignment/Actions Worksheet; Air Force Manpower and Personnel Center (AFMPC) Form 138, Officer Reassignment; Memorandum of Official Contact; Officer Career Objective Statement; Personnel Action Request; Application for Appointment in the AF Reserve; Recall to Active Duty; Supplement to Application for Commission in the United States Air Force (U.S.) Medical Services;

Assignment Notification of Medical Service Officer; Constructive Credit Computation; Personal Interview-USAF Nurse Application; Air Force Institute of Technology (AFIT) Education Plan; Messages; Department of Defense Notification of change in service members official records; Master Personnel Record Fiche; Training/ Specialty Board Certification Records; Continuation Pay Contracts; Specialty Badge Award; Personnel Data Systems (PDS) transactions; Record of Office of Special Investigations (OSI) background checks; Resumes/special applications.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

10 U.S.C. 8013, Secretary of the Air Force: Powers and duties; delegation by; as implemented by Air Force Instruction 36–2105, Officer Classification; Air Force Regulation 36–4, Special Pay for Medical Corps Officers; Air Force Instruction 36–2610, Appointment of Officers in the Regular Air Force; Air Force Instruction 36–2110, Continuation Pay for Dental Corps Officers; Air Force Regulation 36–20, Officer Assignments; Air Force Regulation 36–21, Selective Continuation Program; Air Force Instruction 36–2107, Active Duty Service Commitments (PA); and Air Force Instruction 36–2107, Specified Period of Time Contracts (SPTC) (PA).

PURPOSE(S):

Verify current assignment; verify history of application for: Tour extension, tour curtailment, Specified Period of Time Contract, Indefinite Reserve Status, duty Air Force specialty code change, special duty application, formal school application, change of assignment reporting dates, join spouse application; Use AF Form 24 for obtaining date of birth and place of birth when processing assignment to academy or other highly sensitive area of assignment; to hold messages pertaining to assignment; to hold action notices and career briefs as a result of input from original office and any other office pertaining to an individual. This also includes career briefs and action notices from automatic actions (i.e., available assignment); pay computation; grade computation; to provide background information to answer correspondence.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

In addition to those disclosures generally permitted under 5 U.S.C. 552a(b) of the Privacy Act, these records, or information contained therein, may specifically be disclosed outside the DOD as a routine use pursuant to 5 U.S.C. 552a(b)(3) as follows:

The 'Blanket Routine Uses' published at the beginning of the Air Force's compilation of systems of records notices apply to this system.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Maintained in visible file binders/ cabinets. etc.

RETRIEVABILITY:

Retrieved by name.

SAFEGUARDS:

Records are accessed by custodian of the record system and by person(s) responsible for servicing the record system in performance of their official duties who are properly screened and cleared for need-to-know. Records are stored in locked cabinets or rooms.

RETENTION AND DISPOSAL:

Retained in office files for six months after the individual terminates military service, then destroyed by tearing into pieces, shredding, pulping, macerating, or burning.

SYSTEM MANAGER(S) AND ADDRESS:

Deputy Director of Medical Service Officer Management, Headquarters Air Force Military Personnel Center, 550 C Street W, Randolph Air Force Base, TX 78150–4703.

NOTIFICATION PROCEDURE:

Individuals seeking to determine whether this system of records contains information on themselves should address written inquiries to the Deputy Director of Medical Service Officer Management, Headquarters Air Force Military Personnel Center, 550 C Street W, Randolph Air Force Base, TX 78150–4703.

RECORD ACCESS PROCEDURES:

Individuals seeking to access records about themselves contained in this system should address written requests to the Deputy Director of Medical Service Officer Management, Headquarters Air Force Military Personnel Center, 550 C Street W, Randolph Air Force Base, TX 78150–4703.

CONTESTING RECORD PROCEDURES:

The Air Force rules for accessing records and for contesting contents and appealing initial agency determinations are published in Air Force Instruction 37–132; 32 CFR part 806b; or may be obtained from the system manager.

RECORD SOURCE CATEGORIES:

Applications for appointment, letters written by individual or on individuals by others. Computer print-outs, forms completed by individuals, Personnel Data Systems (PDS) transactions, other information pertinent to assignments or career development of the officer.

EXEMPTIONS CLAIMED FOR THE SYSTEM:

None.

F035 MPC H

SYSTEM NAME:

Medical Opinions on Board for Correction of Military Records Cases *(February 22, 1993, 58 FR 10360).*

CHANGES:

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SYSTEM LOCATION:

Delete entry and replace with 'Headquarters Air Force Military Personnel Center, Deputy Director, Medical Service Officer Management, 550 C Street W, Randolph Air Force Base, TX 78150–4703.'

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AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

Delete entry and replace with '10 U.S.C. 8013, Secretary of the Air Force: Powers and duties; delegation by, and 10 U.S.C. 79, Correction of Military Records; as implemented by Air Force Instruction 36–2603, Air Force Board for Correction of Military Records.'

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STORAGE:

Delete the word 'unlocked.'

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SAFEGUARDS:

Delete entry and replace with 'Records are accessed by person(s) responsible for servicing the record system in performance of their official duties and by authorized personnel who are properly screened and cleared for need-to-know. Records are stored in cabinets and locked rooms.'

* * * * *

SYSTEM MANAGER(S) AND ADDRESS:

Delete entry and replace with 'Deputy Director, Medical Service Officer Management, Headquarters Air Force Military Personnel Center, 550 C Street W, Randolph Air Force Base, TX 78150–4703.'

NOTIFICATION PROCEDURE:

Delete address and replace with 'Deputy Director, Medical Service Officer Management, Headquarters Air Force Military Personnel Center, 550 C Street W, Randolph Air Force Base, TX 78150–4703.'

RECORD ACCESS PROCEDURES:

Delete address and replace with 'Deputy Director, Medical Service Officer Management, Headquarters Air Force Military Personnel Center, 550 C Street W, Randolph Air Force Base, TX 78150–4703.'

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F035 MPC H

SYSTEM NAME:

Medical Opinions on Board for Correction of Military Records Cases (BCMR).

SYSTEM LOCATION:

Headquarters Air Force Military Personnel Center, Deputy Director, Medical Service Officer Management, 550 C Street W, Randolph Air Force Base, TX 78150–4703.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Files are maintained on individuals making application to the Air Force Board for Correction of Military Records on which a medical opinion has been rendered.

CATEGORIES OF RECORDS IN THE SYSTEM:

Contains a copy of the medical advisory opinion rendered on Air Force Board for Correction of Military Records.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

10 U.S.C. 8013, Secretary of the Air Force: Powers and duties; delegation by, and 10 U.S.C. 79, Correction of Military Records; as implemented by Air Force Instruction 36–2603, Air Force Board for Correction of Military Records.

PURPOSE(S):

A historical reference, by name, to previous action taken regarding a specific BCMR application.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

In addition to those disclosures generally permitted under 5 U.S.C. 552a(b) of the Privacy Act, these records, or information contained therein, may specifically be disclosed outside the DOD as a routine use pursuant to 5 U.S.C. 552a(b)(3) as follows:

The 'Blanket Routine Uses' published at the beginning of the Air Force's compilation of systems of records notices apply to this system.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Maintained in file folders in filing cabinets.

RETRIEVABILITY:

Retrieved by name.

SAFEGUARDS:

Records are accessed by person(s) responsible for servicing the record system in performance of their official duties and by authorized personnel who are properly screened and cleared for need-to-know. Records are stored in cabinets and locked rooms.

RETENTION AND DISPOSAL:

Retained in office files for one year or until no longer needed for reference, then destroyed by tearing into pieces, shredding, pulping, macerating, or burning.

SYSTEM MANAGER(S) AND ADDRESS:

Deputy Director, Medical Service Officer Management, Headquarters Air Force Military Personnel Center, 550 C Street W, Randolph Air Force Base, TX 78150–4703.

NOTIFICATION PROCEDURE:

Individuals seeking to determine whether this system of records contains information on themselves should address written inquiries to the Deputy Director, Medical Service Officer Management, Headquarters Air Force Military Personnel Center, 550 C Street W, Randolph Air Force Base, TX 78150–4703.

RECORD ACCESS PROCEDURES:

Individuals seeking to access records about themselves contained in this system should address written requests to the Deputy Director, Medical Service Officer Management, Headquarters Air Force Military Personnel Center, 550 C Street W, Randolph Air Force Base, TX 78150–4703.

CONTESTING RECORD PROCEDURES:

The Air Force rules for accessing records and for contesting contents and appealing initial agency determinations are published in Air Force Instruction 37–132; 32 CFR part 806b; or may be obtained from the system manager.

RECORD SOURCE CATEGORIES:

Information obtained from medical institutions.

EXEMPTIONS CLAIMED FOR THE SYSTEM:

None.

F035 MPC I

SYSTEM NAME:

Office File *(February 22, 1993, 58 FR 10361).*

CHANGES:

SYSTEM IDENTIFIER:

Change system identifier to 'F035 AF DP B.'

SYSTEM NAME:

Delete entry and replace with 'Colonels Assignment File'.

SYSTEM LOCATION:

Delete entry and replace with 'Air Force Colonels Group, Headquarters United States Air Force, 1040 Air Force Pentagon, Washington, DC 20330–1040.'

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CATEGORIES OF RECORDS IN THE SYSTEM:

Delete 'HQ AFMPC/MPCO' in two places and insert 'HQ USAF/DPO.'

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

Delete entry and replace with '10 U.S.C. 8013, Secretary of the Air Force; powers and duties; delegation by; as implemented by Air Force Instruction 36–2402, Officer Evaluations.'

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SYSTEM MANAGER(S) AND ADDRESS:

Delete entry and replace with 'Chief, Air Force Colonels Group, Headquarters United States Air Force, 1040 Air Force Pentagon, Washington, DC 20330–1040.'

NOTIFICATION PROCEDURE:

Delete address and replace with 'Chief, Air Force Colonels Group, Headquarters United States Air Force, 1040 Air Force Pentagon, Washington, DC 20330–1040.'

RECORD ACCESS PROCEDURES:

Delete address and replace with 'Chief, Air Force Colonels Group, Headquarters United States Air Force, 1040 Air Force Pentagon, Washington, DC 20330–1040.'

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F035 AF DP B

SYSTEM NAME:

Colonels Assignment File.

SYSTEM LOCATION:

Air Force Colonels Group, Headquarters United States Air Force, 1040 Air Force Pentagon, Washington, DC 20330–1040.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

All active duty colonels (grade 06) and former active duty colonels (grade 06), who have retired, and who have been retired for 90 days or less.

CATEGORIES OF RECORDS IN THE SYSTEM:

Official photograph; Air Force Form 620, Colonel Resume; copies of correspondence generated by Headquarters USAF/DPO pertaining to the subject of the file; correspondence received by Headquarters USAF/DPO pertaining to the subject of the file;

memoranda of assignment, and related personnel actions contemplated/completed on the subject of the file.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

10 U.S.C. 8013, Secretary of the Air Force; powers and duties; delegation by; as implemented by Air Force Instruction 36–2402, Officer Evaluations.

PURPOSE(S):

Assignment considerations.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

In addition to those disclosures generally permitted under 5 U.S.C. 552a(b) of the Privacy Act, these records, or information contained therein, may specifically be disclosed outside the DOD as a routine use pursuant to 5 U.S.C. 552a(b)(3) as follows:

The 'Blanket Routine Uses' published at the beginning of the Air Force's compilation of systems of records notices apply to this system.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Maintained in visible file binders/cabinets and rotary file bins (lectriever).

RETRIEVABILITY:

Retrieved by name.

SAFEGUARDS:

Records are accessed by custodian of the record system and by person(s) responsible for servicing the record system in performance of their official duties who are properly screened and cleared for need-to-know. Records are stored in locked cabinets or rooms.

RETENTION AND DISPOSAL:

Retain until first anniversary of effective date of retirement/separation from the United States Air Force of the subject of the file, at which point the office file is destroyed by shredding.

SYSTEM MANAGER(S) AND ADDRESS:

Chief, Air Force Colonels Group, Headquarters United States Air Force, 1040 Air Force Pentagon, Washington, DC 20330–1040.

NOTIFICATION PROCEDURE:

Individuals seeking to determine whether information about themselves is contained in this system should address inquiries to the Chief, Air Force Colonels Group, Headquarters United States Air Force, 1040 Air Force Pentagon, Washington, DC 20330–1040.

RECORD ACCESS PROCEDURES:

Individuals seeking to access records about themselves contained in this system should address inquiries to the Chief, Air Force Colonels Group, Headquarters United States Air Force, 1040 Air Force Pentagon, Washington, DC 20330–1040.

CONTESTING RECORD PROCEDURES:

The Air Force rules for accessing records and for contesting contents and appealing initial agency determinations are published in Air Force Instruction 37–132; 32 CFR part 806b; or may be obtained from the system manager.

RECORD SOURCE CATEGORIES:

Subject of the file; AFMPC/MPCO personnel; other Air Force and outside agency originators of correspondence relating to subject of the file, and any additional information which has/could have bearing on assignability of the subject.

EXEMPTIONS CLAIMED FOR THE SYSTEM:

None.

F035 MPC P

SYSTEM NAME:

Recorder's Roster *(February 22, 1993, 58 FR 10364).*

CHANGES:

* * * * *

SYSTEM LOCATION:

Delete entry and replace with 'Headquarters Air Force Military Personnel Center, 550 C Street W, Randolph Air Force Base, TX 78150–4703. Washington National Records Center, Washington, DC 20409.'

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Delete 'CMSs considered for HYT.'

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AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

Delete entry and replace with '10 U.S.C. 531, Original appointment, and 611, Convening of selection boards; as implemented by Air Force Instruction 36–2501, Promotion of Active Duty List Officers.'

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SYSTEM MANAGER(S) AND ADDRESS:

Delete entry and replace with 'Assistant Deputy Chief of Staff for Personnel, Headquarters Air Force Military Personnel Center, 550 C Street W, Randolph Air Force Base, TX 78150–4703.'

NOTIFICATION PROCEDURE:

Delete address and replace with 'Assistant Deputy Chief of Staff for Personnel, Headquarters Air Force Military Personnel Center, 550 C Street W, Randolph Air Force Base, TX 78150–4703.'

RECORD ACCESS PROCEDURES:

Delete entry and replace with 'Assistant Deputy Chief of Staff for Personnel, Headquarters Air Force Military Personnel Center, 550 C Street W, Randolph Air Force Base, TX 78150–4703.'

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F035 MPC P

SYSTEM NAME:

Recorder's Roster.

SYSTEM LOCATION:

Headquarters Air Force Military Personnel Center, 550 C Street W, Randolph Air Force Base, TX 78150–4703. Washington National Records Center, Washington, DC 20409.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Records are maintained on all Air Force officers who are eligible for competitive consideration and officers considered for Regular Air Force appointment and Officers considered for involuntary separation, and any other special board directed by the Secretary of the Air Force or the Chief of Staff.

CATEGORIES OF RECORDS IN THE SYSTEM:

Listing containing record number, name, Social Security Number, date of roster, program control number, component, competitive category, select/non-select status, FOR OFFICIAL USE ONLY statement and name and year of board. A numerical/chronological listing of all changes to competitive file data base after initial build. Listing of special follow items/OPR letters.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

10 U.S.C. 531, Original appointment, and 611, Convening of selection boards; as implemented by Air Force Instruction 36–2501, Promotion of Active Duty List Officers.

PURPOSE(S):

These records are used to determine whether individuals were considered by the convening board.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

In addition to those disclosures generally permitted under 5 U.S.C. 552a(b) of the Privacy Act, these records, or information contained therein, may specifically be disclosed outside the DOD as a routine use

pursuant to 5 U.S.C. 552a(b)(3) as follows:

The 'Blanket Routine Uses' published at the beginning of the Air Force's compilation of systems of records notices apply to this system.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Maintained in visible file binders/cabinets.

RETRIEVABILITY:

Records are accessed by identification of board of consideration and then by inverted Social Security Number of subject by competitive category.

SAFEGUARDS:

Records are accessed by authorized personnel who are properly screened and cleared for need-to-know. Records are stored in locked cabinets or rooms.

RETENTION AND DISPOSAL:

The records are retained in the Selection Board Secretariat for five calendar years and then retired to the National Archives, Washington, DC.

SYSTEM MANAGER(S) AND ADDRESS:

Assistant Deputy Chief of Staff for Personnel, Headquarters Air Force Military Personnel Center, 550 C Street W, Randolph Air Force Base, TX 78150–4703.

NOTIFICATION PROCEDURE:

Individuals seeking to determine whether this system of records contains information on themselves should address written inquiries to the Assistant Deputy Chief of Staff for Personnel, Headquarters Air Force Military Personnel Center, 550 C Street W, Randolph Air Force Base, TX 78150–4703.

RECORD ACCESS PROCEDURES:

Individuals seeking to access records about themselves contained in this system should address written requests to the Assistant Deputy Chief of Staff for Personnel, Headquarters Air Force Military Personnel Center, 550 C Street W, Randolph Air Force Base, TX 78150–4703.

Request must include name, grade, Social Security Number, board identification, competitive category, and zone of consideration as applicable.

CONTESTING RECORD PROCEDURES:

The Air Force rules for accessing records and for contesting contents and appealing initial agency determinations are published in Air Force Instruction 37–132; 32 CFR part 806b; or may be obtained from the system manager.

RECORD SOURCE CATEGORIES:

The information in these records is extracted from the Selection Board Support File, and from data compiled from individual board member inputs.

EXEMPTIONS CLAIMED FOR THE SYSTEM:

None.

F050 AFCC A

SYSTEM NAME:

United States Air Force Air Traffic Control (ATC) Certification and Withdrawal Documentation *(February 22, 1993, 58 FR 10390).*

CHANGES:

SYSTEM IDENTIFIER:

Change system identifier to 'F050 AFFSA A.'

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SYSTEM LOCATION:

Delete entry and replace with 'Headquarters Air Force Flight Standards Agency, headquarters of major commands and at all levels down to and including Air Force installations. Official mailing addresses are published as an appendix to the Air Force's compilation of record systems notices.'

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AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

Delete entry and replace with '10 U.S.C. 8013, Secretary of the Air Force: Powers and duties; delegation by, as implemented by Air Force Instruction 13–203, Air Traffic Control, and E.O. 9397.'

* * * * *

SYSTEM MANAGER(S) AND ADDRESS:

Delete entry and replace with 'Commander, Air Force Flight Standards Agency, Scott Air Force Base, IL 62225–5219.'

NOTIFICATION PROCEDURE:

Delete address and replace with 'Commander, Air Force Flight Standards Agency, Scott Air Force Base, IL 62225–5219.'

RECORD ACCESS PROCEDURES:

Delete address and replace with 'Commander, Air Force Flight Standards Agency, Scott Air Force Base, IL 62225–5219.'

* * * * *

F050 AFFSA A

SYSTEM NAME:

USAF Air Traffic Control (ATC) Certification and Withdrawal Documentation.

SYSTEM LOCATION:

Headquarters Air Force Flight Standards Agency, headquarters of major commands and at all levels down to and including Air Force installations. Official mailing addresses are published as an appendix to the Air Force's compilation of record systems notices.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Air Force active duty military personnel, and Air Force Reserve and Air National Guard personnel assigned ATC duties.

CATEGORIES OF RECORDS IN THE SYSTEM:

Records on individuals by name and Social Security Number, Air Traffic Control Certificate Numbers (ATCS) military status (active duty, reserve, or air guard), requested action (issue, reissue, or cancellation of certificate), and justification. Contains documentation compiled by requesting unit to justify withdrawal of the ATCS. Includes evaluation by medical authorities; Staff Judge Advocate (legal); Office of Special Investigation results; serious incident reports; and statements by supervisory personnel, co-workers and the individual. Contains copies of officer effectiveness/airman performance (OER/APR) reports and unfavorable information files. Includes headquarters staff evaluation and all files maintained by the system user. Computer reports pertaining to withdrawal of ATCS, Certificates, master roster of ATCS certificate members and Air Traffic Control experience level report.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

10 U.S.C. 8013, Secretary of the Air Force: Powers and duties; delegation by, as implemented by Air Force Instruction 13–203, Air Traffic Control, and E.O. 9397.

PURPOSE(S):

Documentation used to evaluate request for withdrawal of ATCS certification. Permits immediate access to name, Social Security Number, certificate number, date of issuance, and category of service. A master alphanumeric roster is maintained at Headquarters AFCC/DOOF and the units maintain certificate information in the individual's on-the-job training record.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

In addition to those disclosures generally permitted under 5 U.S.C. 552a(b) of the Privacy Act, these records, or information contained

therein, may specifically be disclosed outside the DOD as a routine use pursuant to 5 U.S.C. 552a(b)(3) as follows:

The 'Blanket Routine Uses' published at the beginning of the Air Force's compilation of systems of records notices apply to this system.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Maintained in file folders note books/ binders and on computer paper printouts and microfiche.

RETRIEVABILITY:

Retrieved by name or Social Security Number.

SAFEGUARDS:

Records are accessed by custodian of the record system and by person(s) responsible for servicing the record system in performance of their official duties who are properly screened and cleared for need-to-know. Records are stored in locked cabinets or rooms. Records are controlled by computer system software.

RETENTION AND DISPOSAL:

Individual withdrawal microfiche case files are kept for 6 years after end of the year in which case closed. Official withdrawal book, long, and to by name and Social Security Number will be kept for 20 years. Other computer reports are superseded monthly. Files are destroyed by tearing into pieces, shredding, pulping, macerating of burning.

Retained for one year after end of year in which the case was closed, transferred to a staging area for one additional year, then destroyed by tearing into pieces, shredding, pulping, macerating, or burning.

SYSTEM MANAGER(S) AND ADDRESS:

Commander, Air Force Flight Standards Agency, Scott Air Force Base, IL 62225–5219.

NOTIFICATION PROCEDURE:

Individuals seeking to determine whether this system of records contains information on themselves should address written inquiries to the Commander, Air Force Flight Standards Agency, Scott Air Force Base, IL 62225–5219.

RECORD ACCESS PROCEDURES:

Individuals seeking to access records about themselves contained in this system should address written requests to the Commander, Air Force Flight Standards Agency, Scott Air Force Base, IL 62225–5219.

CONTESTING RECORD PROCEDURES:

The Air Force rules for accessing records and for contesting contents and appealing initial agency determinations are published in Air Force Instruction 37–132; 32 CFR part 806b; or may be obtained from the system manager.

RECORD SOURCE CATEGORIES:

Information obtained from source documents such as reports, and from medical institutions, trade associations, police and investigating officers, state and local governments, and witnesses.

EXEMPTIONS CLAIMED FOR THE SYSTEM:

None.

F050 AFCC C

SYSTEM NAME:

Individual Academic Training Record *(February 22, 1993, 58 FR 10391).*

CHANGES:

SYSTEM IDENTIFIER:

Change system identifier to 'F050 AFC4A A.'

* * * * *

SYSTEM LOCATION:

Delete entry and replace with 'Air Force Command, Control, Communications and Computers Agency (AFC4A) System Evaluation School, 1815 Operational Test and Evaluation Squadron, Wright-Paterson Air Force Base, OH 45433–6346; AFC4A Engineering Installation Academy, Communication Systems Center, Tinker Air Force Base, OK 73145–6343; AFC4A Engineering Installation organizations. Official mailing addresses are published as an appendix to the Air Force's compilation of systems of records notices.'

* * * * *

RETRIEVABILITY:

Add to end of entry 'and/or class number.'

* * * * *

SYSTEM MANAGER(S) AND ADDRESS:

Delete entry and replace with 'Commandant, AFC4A System Evaluation School, 1815 Operational Test and Evaluation Squadron, Wright-Paterson Air Force Base, OH 45433–6346; Commandant, AFC4A Engineering Installation Academy, Communication Systems Center, Tinker Air Force Base, OK 73145–6343, and Commandants, AFC4A Engineering Installation organizations. Official mailing addresses are published as an appendix to the Air Force's compilation of systems of records notices.'

NOTIFICATION PROCEDURE:

Delete addresses and replace with 'Commandant, AFC4A System Evaluation School, 1815 Operational Test and Evaluation Squadron, Wright-Paterson Air Force Base, OH 45433–6346; Commandant, AFC4A Engineering Installation Academy, Communication Systems Center, Tinker Air Force Base, OK 73145–6343, or Commandants, AFC4A Engineering Installation organizations. Official mailing addresses are published as an appendix to the Air Force's compilation of systems of records notices.'

RECORD ACCESS PROCEDURES:

Delete addresses and replace with 'Commandant, AFC4A System Evaluation School, 1815 Operational Test and Evaluation Squadron, Wright-Paterson Air Force Base, OH 45433–6346; Commandant, AFC4A Engineering Installation Academy, Communication Systems Center, Tinker Air Force Base, OK 73145–6343, or Commandants, AFC4A Engineering Installation organizations. Official mailing addresses are published as an appendix to the Air Force's compilation of systems of records notices.'

* * * * *

F050 AFC4A A

SYSTEM NAME:

Individual Academic Training Record.

SYSTEM LOCATION:

Air Force Command, Control, Communications and Computers Agency (AFC4A) System Evaluation School, 1815 Operational Test and Evaluation Squadron, Wright-Paterson Air Force Base, OH 45433–6346; AFC4A Engineering Installation Academy, Communication Systems Center, Tinker Air Force Base, OK 73145–6343; AFC4A Engineering Installation organizations. Official mailing addresses are published as an appendix to the Air Force's compilation of systems of records notices.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Active duty military, Air Force Reserve, Air National Guard, Army National Guard, and Department of Defense civilian personnel, and others who apply for this training.

CATEGORIES OF RECORDS IN THE SYSTEM:

Personnel index; class pre-graduation/ graduation roster; absentee report; attendance record; student questionnaires, individual academic standing; record of individual training.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

10 U.S.C. 8013, Secretary of the Air Force: Powers and duties; delegation by.

PURPOSE(S):

To record emergency data and course completion information, and to report student absences to the school commandant.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

In addition to those disclosures generally permitted under 5 U.S.C. 552a(b) of the Privacy Act, these records, or information contained therein, may specifically be disclosed outside the DOD as a routine use pursuant to 5 U.S.C. 552a(b)(3) as follows:

The 'Blanket Routine Uses' published at the beginning of the Air Force's compilation of systems of records notices apply to this system.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Maintained in file folder and card files, and on computer and computer output products.

RETRIEVABILITY:

Retrieved by name and/or class number.

SAFEGUARDS:

Records are accessed by custodian of the records system and by person(s) responsible for servicing the records system in performance of official duties. Stored in file cabinet. Automated records are controlled by computer system software.

RETENTION AND DISPOSAL:

Retained for ten years after individual completes or discontinues training course. Records of individual training at EI organizations are retained until individual no longer performs EI duties, then are destroyed.

SYSTEM MANAGER(S) AND ADDRESS:

Commandant, AFC4A System Evaluation School, 1815 Operational Test and Evaluation Squadron, Wright-Paterson Air Force Base, OH 45433–6346; Commandant, AFC4A Engineering Installation Academy, Communication Systems Center, Tinker Air Force Base, OK 73145–6343, and Commandants, AFC4A Engineering Installation organizations. Official mailing addresses are published as an appendix to the Air Force's compilation of systems of records notices.

NOTIFICATION PROCEDURE:

Individuals seeking to determine whether this system of records contains information on themselves should address written inquiries to the Commandant, AFC4A System Evaluation School, 1815 Operational Test and Evaluation Squadron, Wright-Paterson Air Force Base, OH 45433–6346; Commandant, AFC4A Engineering Installation Academy, Communication Systems Center, Tinker Air Force Base, OK 73145–6343, or Commandants, AFC4A Engineering Installation organizations. Official mailing addresses are published as an appendix to the Air Force's compilation of systems of records notices.

RECORD ACCESS PROCEDURES:

Individuals seeking to access records about themselves contained in this system should address written requests to the Commandant, AFC4A System Evaluation School, 1815 Operational Test and Evaluation Squadron, Wright-Paterson Air Force Base, OH 45433–6346; Commandant, AFC4A Engineering Installation Academy, Communication Systems Center, Tinker Air Force Base, OK 73145–6343, or Commandants, AFC4A Engineering Installation organizations. Official mailing addresses are published as an appendix to the Air Force's compilation of systems of records notices.

CONTESTING RECORD PROCEDURES:

The Air Force rules for accessing records and for contesting contents and appealing initial agency determinations are published in Air Force Instruction 37–132; 32 CFR part 806b; or may be obtained from the system manager.

RECORD SOURCE CATEGORIES:

Information from individuals and instructors.

EXEMPTIONS CLAIMED FOR THE SYSTEM:

None.

F066 AF A

SYSTEM NAME:

Maintenance Management Information and Control System (MMICS) *(February 22, 1993, 58 FR 10413).*

CHANGES:

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Change system name to 'Core Automated Maintenance System (CAMS).'

SYSTEM LOCATION:

Delete entry and replace with 'All Air Force installations utilizing CAMS. Official mailing addresses are published as an appendix to the Air Force's compilation of record systems notices.'

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CATEGORIES OF RECORDS IN THE SYSTEM:

Delete entry and replace with 'Maintenance personnel records related to an individual on-the-job training certification and qualifications.'

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

Delete entry and replace with '10 U.S.C. 8013, Secretary of the Air Force: Powers and duties; delegation by; Air Force Instruction 21–101, Air Force Aircraft and Equipment Maintenance; Air Force Instruction 36–2232, Maintenance Training Policy, and E.O. 9397.'

PURPOSE(S):

Change second sentence to read 'Used by work center supervisors maintenance training and administrative personnel and other members of the chief of maintenance staff (or equivalent) to maintain basic data relating to an individual's training certification and qualifications and to monitor the overall manning status of an organization.'

* * * * *

RETRIEVABILITY:

Delete entry and replace with 'Retrieved by name, man number, or Social Security Number.'

* * * * *

RETENTION AND DISPOSAL:

Add to end of entry 'Computer records are destroyed by erasing, deleting or overwriting.'

SYSTEM MANAGER(S) AND ADDRESS:

Delete 'MMICS' and insert 'CAMS.'

NOTIFICATION PROCEDURE:

Delete 'MMICS' and insert 'CAMS.'

RECORD ACCESS PROCEDURES:

Delete 'MMICS' and insert 'CAMS.'

* * * * *

F066 AF A

SYSTEM NAME:

Core Automated Maintenance System (CAMS).

SYSTEM LOCATION:

All Air Force installation utilizing CAMS. Official mailing addresses are published as an appendix to the Air Force's compilation of record systems notices.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Individuals assigned to organizations involved in the maintenance of aircraft missiles, communications electronics and associated equipment.

CATEGORIES OF RECORDS IN THE SYSTEM:

Maintenance personnel records related to an individual on-the-job training certification and qualifications.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

10 U.S.C. 8013, Secretary of the Air Force: Powers and duties; delegation by; Air Force Instruction 21–101, Air Force Aircraft and Equipment Maintenance; Air Force Instruction 36–2232, Maintenance Training Policy, and E.O. 9397.

PURPOSE(S):

Used to establish and maintain data and on-the-job training records pertaining to a specific individual assigned to a maintenance organization. Used by work center supervisors maintenance training and administrative personnel and other members of the chief of maintenance staff (or equivalent) to maintain basic data relating to an individual's training certification and qualifications and to monitor the overall manning status of an organization.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

In addition to those disclosures generally permitted under 5 U.S.C. 552a(b) of the Privacy Act, these records, or information contained therein, may specifically be disclosed outside the DOD as a routine use pursuant to 5 U.S.C. 552a(b)(3) as follows:

The 'Blanket Routine Uses' published at the beginning of the Air Force's compilation of systems of records notices apply to this system.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Maintained on disks or tapes.

RETRIEVABILITY:

Retrieved by name, man number, or Social Security Number.

SAFEGUARDS:

Records are accessed by person(s) responsible for servicing the record system in performance of their official duties. Records are controlled by computer system software.

RETENTION AND DISPOSAL:

Maintained until purpose has been served or for 1 month whichever is sooner then destroyed by tearing into pieces, pulping, burning, shredding, or macerating. Computer records are destroyed by erasing, deleting or overwriting.

SYSTEM MANAGER(S) AND ADDRESS:

Non-commissioned officer in charge of the maintenance documentation or files maintenance section at each unit utilizing CAMS. Official mailing addresses are published as an appendix to the Air Force's compilation of systems of records notices.

NOTIFICATION PROCEDURE:

Individuals seeking to determine whether information about themselves is contained in this system should address written inquiries to or visit the Non-commissioned officer in charge of the maintenance documentation or files maintenance section at each unit utilizing CAMS. Official mailing addresses are published as an appendix to the Air Force's compilation of systems of records notices.

RECORD ACCESS PROCEDURES:

Individuals seeking access to information about themselves contained in this system should address written inquiries to or visit the Non-commissioned officer in charge of the maintenance documentation or files maintenance section at each unit utilizing CAMS. Official mailing addresses are published as an appendix to the Air Force's compilation of systems of records notices.

CONTESTING RECORD PROCEDURES:

The Air Force rules for accessing records and for contesting contents and appealing initial agency determinations are published in Air Force Instruction 37–132; 32 CFR part 806b; or may be obtained from the system manager.

RECORD SOURCE CATEGORIES:

Information obtained from automated system interfaces and source documents such as reports.

EXEMPTIONS CLAIMED FOR THE SYSTEM:

None.

F100 AFCC A

SYSTEM NAME:

Military Affiliate Radio System (MARS) Member Records *(February 22, 1993, 58 FR 10424).*

CHANGES:

SYSTEM IDENTIFIER:

Change system identifier to 'F100 AFC4A A.'

* * * * *

SYSTEM LOCATION:

Delete entry and replace with 'Air Force Command, Control, Communications and Computers Agency (AFC4A), and at MARS member stations. Official mailing addresses are published as an appendix to the Air Force's compilation of record systems notices.'

* * * * *

CATEGORIES OF RECORDS IN THE SYSTEM:

Delete entry and replace with 'MARS Personnel Action Notification and Application for Membership in Military Affiliate Radio System. Information includes individuals name, MARS call sign, amateur call sign, mailing address, Federal Communications Commission (FCC) license class, military status, telephone number, and date of birth.'

* * * * *

PURPOSE(S):

Delete entry and replace with 'To identify MARS members, to describe and update information concerning members, to assign call signs and designator, mailing address, amateur license, telephone number, and responsibilities.'

* * * * *

STORAGE:

Delete 'file folders' and insert 'card files.'

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RETENTION AND DISPOSAL:

Delete first sentence and replace with 'At AFC4A, retained until termination of membership, then destroyed by tearing to pieces, shredding, pulping, macerating or burning.'

SYSTEM MANAGER(S) AND ADDRESS:

Delete entry and replace with 'Deputy Chief of Staff, Systems and Procedures, (AFC4A/SYXR), 203 W. Losey Street, Room 1020, Scott Air Force Base, IL 62225–5219.'

NOTIFICATION PROCEDURE:

Delete address and replace with 'Deputy Chief of Staff, Systems and Procedures, (AFC4A/SYXR), 203 W. Losey Street, Room 1020, Scott Air Force Base, IL 62225–5219.'

RECORD ACCESS PROCEDURES:

Delete address and replace with 'Deputy Chief of Staff, Systems and Procedures, (AFC4A/SYXR), 203 W. Losey Street, Room 1020, Scott Air Force Base, IL 62225–5219.'

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F100 AFC4A A

SYSTEM NAME:

Military Affiliate Radio System (MARS) Member Records.

SYSTEM LOCATION:

Air Force Command, Control, Communications and Computers

Agency (AFC4A), and at MARS member stations. Official mailing addresses are published as an appendix to the Air Force's compilation of record systems notices.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Amateur Radio Operators licensed by United States Air Force (USAF) Military Affiliate Radio System.

CATEGORIES OF RECORDS IN THE SYSTEM:

MARS Personnel Action Notification and Application for Membership in Military Affiliate Radio System. Information includes individuals name, MARS call sign, amateur call sign, mailing address, Federal Communications Commission (FCC) license class, military status, telephone number, and date of birth.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

10 U.S.C. 8013, Secretary of Air Force, powers and duties; delegation by; as implemented by Air Force Regulation 700–17, Military Affiliate Radio System (MARS).

PURPOSE(S):

To identify MARS members, to describe and update information concerning members, to assign call signs and designator, mailing address, amateur license, telephone number, and responsibilities.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

In addition to those disclosures generally permitted under 5 U.S.C. 552a(b) of the Privacy Act, these records, or information contained therein, may specifically be disclosed outside the DOD as a routine use pursuant to 5 U.S.C. 552a(b)(3) as follows:

The 'Blanket Routine Uses' published at the beginning of the Air Force's compilation of systems of records notices apply to this system.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Maintained in card files, in computers and on computer output products.

RETRIEVABILITY:

Retrieved by name, by call sign or designator and geographic location.

SAFEGUARDS:

Records are accessed by person(s) responsible for servicing the record system in performance of their official duties and by authorized personnel who are properly screened and cleared for need-to-know. Records are stored in locked rooms and cabinets. Those in computer storage devices are protected by computer system software.

RETENTION AND DISPOSAL:

At AFC4A, retained until termination of membership, then destroyed by tearing to pieces, shredding, pulping, macerating or burning. At Military Affiliate Radio System stations, retained in office files until reassignment or termination of membership. Records are destroyed by tearing into pieces, shredding, pulping, macerating or burning. Computer records are destroyed by erasing, deleting or overwriting.

SYSTEM MANAGER(S) AND ADDRESS:

Deputy Chief of Staff, Systems and Procedures, (AFC4A/SYXR), 203 W. Losey Street, Room 1020, Scott Air Force Base, IL 62225–5219.

NOTIFICATION PROCEDURE:

Individuals seeking to determine whether this system of records contains information on themselves should address written inquiries to the Deputy Chief of Staff, Systems and Procedures, (AFC4A/SYXR), 203 W. Losey Street, Room 1020, Scott Air Force Base, IL 62225–5219.

RECORD ACCESS PROCEDURES:

Individuals seeking to access records about themselves contained in this system should address written requests to the Deputy Chief of Staff, Systems and Procedures, (AFC4A/SYXR), 203 W. Losey Street, Room 1020, Scott Air Force Base, IL 62225–5219.

CONTESTING RECORD PROCEDURES:

The Air Force rules for accessing records and for contesting contents and appealing initial agency determinations are published in Air Force Instruction 37–132; 32 CFR part 806b; or may be obtained from the system manager.

RECORD SOURCE CATEGORIES:

Individual members and Military Affiliate Radio System officials.

EXEMPTIONS CLAIMED FOR THE SYSTEM:

None.

F125 AF A

SYSTEM NAME:

Correction and Rehabilitation Records *(February 22, 1993, 58 FR 10442).*

CHANGES:

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SYSTEM LOCATION:

Delete entry and replace with 'Headquarters, Air Force Security Police Agency, 8201 H Avenue, Kirtland Air Force Base, NM 87117–5664, and elements; the Air Force Clemency and Parole Board, Office of the Secretary of the Air Force Personnel Council, 1662 Air Force Pentagon, Washington, DC 20330–1662.

Chief of Security Police at local installation where individual is assigned. Official mailing addresses are published as an appendix to the Air Force's compilation of systems of records notices.

Records may also be at Headquarters, United States Air Force, Chief of Security Police, 1340 Air Force Pentagon, Washington, DC 20330–1340, and at the National Personnel Records Center, Military Personnel Records, 9700 Page Boulevard, St. Louis, MO 63132–2001.'

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Delete entry and replace with 'Individuals placed in confinement at an installation or federal prison as the result of military criminal conviction. Individuals placed in confinement or rehabilitation and assigned to Headquarters, Air Force Security Police Agency (AFSPA) or any element of operating location.'

* * * * *

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

Delete entry and replace with '10 U.S.C. 8013, Secretary of the Air Force: Powers and duties; delegation by, as implemented by Air Force Instruction 31–205, Operation and Administration of Air Force Confinement and Correction Programs and Facilities, and E.O. 9397.'

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STORAGE:

Delete 'in microfilm.'

RETRIEVABILITY:

Delete entry and replace with 'Retrieved by any or a combination of name, Social Security Number and fingerprint classification, or by date of board hearing.'

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RETENTION AND DISPOSAL:

Delete entry and replace with 'Depending on the type of record within the system, it is either destroyed after release of the prisoner, maintained for one year after the release of the individual, or retained in the files at the facility in which the individual was confined for three months, after which time the record is forwarded to Headquarters, Air Force Security Police Agency, 8201 H Avenue, Kirtland Air

Force Base, NM 87117–5664. Within two years after receipt, records are sent to the National Personnel Records Center, Military Personnel Records, St. Louis, MO.'

SYSTEM MANAGER(S) AND ADDRESS:

Delete entry and replace with 'Director of Correction, Headquarters, Air Force Security Police Agency, 8201 H Avenue, Kirtland Air Force Base, NM 87117–5664. Executive Secretary, Air Force Clemency and Parole Board, Office of the Secretary of the Air Force Personnel Council, 1662 Air Force Pentagon, Washington, DC 20330–1662. Chief of Security Police at local installation where individual is assigned. Official mailing addresses are published as an appendix to the Air Force's compilation of systems of records notices.'

NOTIFICATION PROCEDURE:

Delete addresses and replace with 'Director of Correction, Headquarters, Air Force Security Police Agency, 8201 H Avenue, Kirtland Air Force Base, NM 87117–5664; Executive Secretary, Air Force Clemency and Parole Board, Office of the Secretary of the Air Force Personnel Council, 1662 Air Force Pentagon, Washington, DC 20330–1662, or Chief of Security Police at local installation where individual was last assigned. Official mailing addresses are published as an appendix to the Air Force's compilation of systems of records notices.'

RECORD ACCESS PROCEDURES:

Delete addresses and replace with 'Director of Correction, Headquarters, Air Force Security Police Agency, 8201 H Avenue, Kirtland Air Force Base, NM 87117–5664; Executive Secretary, Air Force Clemency and Parole Board, Office of the Secretary of the Air Force Personnel Council, 1662 Air Force Pentagon, Washington, DC 20330–1662, or Chief of Security Police at local installation where individual was last assigned. Official mailing addresses are published as an appendix to the Air Force's compilation of systems of records notices.'

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F125 AF A

SYSTEM NAME:

Correction and Rehabilitation Records.

SYSTEM LOCATION:

Headquarters, Air Force Security Police Agency, 8201 H Avenue, Kirtland Air Force Base, NM 87117–5664, and elements; the Air Force Clemency and Parole Board, Office of the Secretary of the Air Force Personnel Council, 1662 Air Force Pentagon, Washington, DC 20330–1662.

Chief of Security Police at local installation where individual is assigned. Official mailing addresses are published as an appendix to the Air Force's compilation of systems of records notices. Records may also be at Headquarters, United States Air Force, Chief of Security Police, 1340 Air Force Pentagon, Washington, DC 20330–1340, and at the National Personnel Records Center, Military Personnel Records, 9700 Page Boulevard, St. Louis, MO 63132–2001.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Individuals placed in confinement at an installation or federal prison as the result of military criminal conviction. Individuals placed in confinement or rehabilitation and assigned to Headquarters, Air Force Security Police Agency (AFSPA) or any element of operating location.

CATEGORIES OF RECORDS IN THE SYSTEM:

Prisoner personnel records consisting of confinement orders, release orders, personal history records, medical examiners report, request and receipt for health and comfort supplies, recommendations for disciplinary action, inspection records, prisoner classification summaries and records pertaining to any clemency/parole actions.

Corrections officers records including personal deposit fund records and related documents, disciplinary books, correction facility blotters and visitor registers; requests for interview and evaluation reports; prisoner records consisting of daily strength records and reports of escaped and returned from escaped prisoners.

Psychological or rehabilitation test records.

Clemency and Parole Board decisional documents and related records reflecting the action of the Board, the Board's recommendations to the Secretary and the rationale for actions taken or proposed.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

10 U.S.C. 8013, Secretary of the Air Force: Powers and duties; delegation by, as implemented by Air Force Instruction 31–205, Operation and Administration of Air Force Confinement and Correction Programs and Facilities, and E.O. 9397.

PURPOSE(S):

To maintain a life file on the individual as a prisoner on an Air Force installation, or as an Air Force prisoner serving a sentence in a federal prison.

The records are used to establish background for either disciplinary or good conduct action as well as general administration uses of the records concerning health and welfare of the individual, as well as clemency and parole actions.

Historical records in microfilm are used as a research data base.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

In addition to those disclosures generally permitted under 5 U.S.C. 552a(b) of the Privacy Act, these records, or information contained therein, may specifically be disclosed outside the DOD as a routine use pursuant to 5 U.S.C. 552a(b)(3) as follows:

Information may also be disclosed Federal, state, and local law enforcement and investigation agencies for investigation and possible criminal prosecution, civil court actions or regulatory orders, confinement/correctional agencies for use in the administration of correctional programs, including custody classification, employment, training and educational assignments, treatment programs, clemency, restoration to duty or parole actions, verification of offender's criminal records, employment records, and social histories.

The 'Blanket Routine Uses' published at the beginning of the Air Force's compilation of systems of records notices apply to this system.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Maintained in file folders, in notebooks/binders, in card files, on computer and computer output products, and as photographs.

RETRIEVABILITY:

Retrieved by any or a combination of name, Social Security Number and fingerprint classification, or by date of board hearing.

SAFEGUARDS:

Records are accessed by custodian of the record system and by person(s) responsible for servicing the record system in performance of their official duties. Records are stored in locked cabinets or rooms and controlled by visitor registers.

RETENTION AND DISPOSAL:

Depending on the type of record within the system, it is either destroyed

after release of the prisoner, maintained for one year after the release of the individual, or retained in the files at the facility in which the individual was confined for three months, after which time the record is forwarded to Headquarters, Air Force Security Police Agency, 8201 H Avenue, Kirtland Air Force Base, NM 87117–5664. Within two years after receipt, records are sent to the National Personnel Records Center, Military Personnel Records, St. Louis, MO.

SYSTEM MANAGER(S) AND ADDRESS:

Director of Correction, Headquarters, Air Force Security Police Agency, 8201 H Avenue, Kirtland Air Force Base, NM 87117–5664. Executive Secretary, Air Force Clemency and Parole Board, Office of the Secretary of the Air Force Personnel Council, 1662 Air Force Pentagon, Washington, DC 20330–1662. Chief of Security Police at local installation where individual is assigned. Official mailing addresses are published as an appendix to the Air Force's compilation of systems of records notices.

NOTIFICATION PROCEDURE:

Individuals seeking to determine whether this system of records contains information on themselves should address written inquiries to the Director of Correction, Headquarters, Air Force Security Police Agency, 8201 H Avenue, Kirtland Air Force Base, NM 87117–5664; Executive Secretary, Air Force Clemency and Parole Board, Office of the Secretary of the Air Force Personnel Council, 1662 Air Force Pentagon, Washington, DC 20330–1662, or Chief of Security Police at local installation where individual was last assigned. Official mailing addresses are published as an appendix to the Air Force's compilation of systems of records notices.

RECORD ACCESS PROCEDURES:

Individuals seeking access to records about themselves contained in this system should address written requests to the Director of Correction, Headquarters, Air Force Security Police Agency, 8201 H Avenue, Kirtland Air Force Base, NM 87117–5664; Executive Secretary, Air Force Clemency and Parole Board, Office of the Secretary of the Air Force Personnel Council, 1662 Air Force Pentagon, Washington, DC 20330–1662, or Chief of Security Police at local installation where individual was last assigned. Official mailing addresses are published as an appendix to the Air Force's compilation of systems of records notices.

CONTESTING RECORD PROCEDURES:

The Air Force rules for accessing records and for contesting contents and appealing initial agency determinations are published in Air Force Instruction 37–132; 32 CFR part 806b; or may be obtained from the system manager.

RECORD SOURCE CATEGORIES:

Financial and medical institutions, police and investigative officers, state or local government, witnesses or source documents.

Installation level confinement facilities, courts-martial, and court-martial reviews, and submissions received directly from, or in behalf of the prisoner.

EXEMPTIONS CLAIMED FOR THE SYSTEM:

Portions of this system may be exempt pursuant to 5 U.S.C. 552a(j)(2), as applicable.

An exemption rule for this record system has been promulgated in accordance with the requirements of 5 U.S.C. 553(b)(1), (2), and (3), (c) and (e) and published in 32 CFR part 806b. For additional information contact the system manager.

F160 MPC A

SYSTEM NAME:

Medical Assignment Limitation Record System *(February 22, 1993, 58 FR 10458).*

CHANGES:

* * * * *

SYSTEM LOCATION:

Delete entry and replace with 'Headquarters Air Force Military Personnel Center, Medical Service Officer Utilization Division, 550 C Street W, Randolph Air Force Base, TX 78150–4703.'

* * * * *

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

Delete entry and replace with '10 U.S.C. 8013, Secretary of the Air Force: Powers and duties; delegation by and implemented by Air Force Instruction 36–2902, Physical Evaluation for Retention, Retirement and Separation; Air Force Instruction 36–2110. '

* * * * *

SAFEGUARDS:

Add to end of entry 'Records are stored in locked rooms and cabinets.'

* * * * *

SYSTEM MANAGER(S) AND ADDRESS:

Delete entry and replace with 'Headquarters Air Force Military Personnel Center, Chief, Medical Service Officer Utilization Division, Randolph Air Force Base, TX 78150–6001.'

NOTIFICATION PROCEDURE:

Delete address and replace with 'Headquarters Air Force Military Personnel Center, Chief, Medical Service Officer Utilization Division, Randolph Air Force Base, TX 78150–6001.'

RECORD ACCESS PROCEDURES:

Delete entry and replace with 'Headquarters Air Force Military Personnel Center, Chief, Medical Service Officer Utilization Division, Randolph Air Force Base, TX 78150–6001.'

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F160 MPC A

SYSTEM NAME:

Medical Assignment Limitation Record System.

SYSTEM LOCATION:

Headquarters Air Force Military Personnel Center, Medical Service Officer Utilization Division, 550 C Street W, Randolph Air Force Base, TX 78150–4703.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

All Air Force members whose cases have been presented to a Medical Evaluation Board and were returned to duty by Medical Evaluation Board or Physical Evaluation Board action and have been assigned an Assignment limitation Code 'C.'

CATEGORIES OF RECORDS IN THE SYSTEM:

Medical Evaluation Board, Report of Medical Examination, Report of Medical History, Narrative Summary, Clinical Record Consultation Sheet, Electrocardiographic Record, etc.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

10 U.S.C. 8013, Secretary of the Air Force: Powers and duties; delegation by and implemented by Air Force Instruction 36–2902, Physical Evaluation for Retention, Retirement and Separation; Air Force Instruction 36–2110.

PURPOSE(S):

To determine if previous action has been taken by the system manager, and what the previous disposition was.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

In addition to those disclosures generally permitted under 5 U.S.C. 552a(b) of the Privacy Act, these records, or information contained

therein, may specifically be disclosed outside the DOD as a routine use pursuant to 5 U.S.C. 552a(b)(3) as follows:

The 'Blanket Routine Uses' published at the beginning of the Air Force's compilation of systems of records notices apply to this system.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Maintained in file folders.

RETRIEVABILITY:

Retrieved by name.

SAFEGUARDS:

Records are accessed by person(s) responsible for servicing the record system in performance of their official duties. Records are stored in locked rooms and cabinets.

RETENTION AND DISPOSAL:

Retained in office files for two years or no longer needed for reference, then destroyed by tearing into pieces, shredding, pulping, macerating, or burning.

SYSTEM MANAGER(S) AND ADDRESS:

Headquarters Air Force Military Personnel Center, Chief, Medical Service Officer Utilization Division, Randolph Air Force Base, TX 78150–6001.

NOTIFICATION PROCEDURE:

Individuals seeking to determine whether this system of records contains information on themselves should address written inquiries to Headquarters Air Force Military Personnel Center, Chief, Medical Service Officer Utilization Division, Randolph Air Force Base, TX 78150–6001.

RECORD ACCESS PROCEDURES:

Individuals seeking to access records about themselves contained in this system should address written requests to Headquarters Air Force Military Personnel Center, Chief, Medical Service Officer Utilization Division, Randolph Air Force Base, TX 78150–6001.

CONTESTING RECORD PROCEDURES:

The Air Force rules for accessing records and for contesting contents and appealing initial agency determinations are published in Air Force Instruction 37–132; 32 CFR part 806b; or may be obtained from the system manager.

RECORD SOURCE CATEGORIES:

Information obtained from medical institutions.

EXEMPTIONS CLAIMED FOR THE SYSTEM:

None.

F161 AF SG A

SYSTEM NAME:

Air Force Aerospace Physiology Training Programs *(February 22, 1993, 58 FR 10459).*

CHANGES:

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SYSTEM LOCATION:

Delete entry and replace with 'Chamber Flight Records located at Human Systems Center, Data Sciences Branch, 2510 Kennedy Circle, Suite 3, Brooks Air Force Base, TX 78235–5199; Physiological Training monthly reports at each Air Force Physiological Training Unit; Headquarters Air Force Medical Operation Agency, 170 Luke Avenue, Suite 400, Bolling Air Force Base, DC 20332–5113; Medical records at Armstrong Laboratory, Aerospace Medicine Directorate, Hyperbaric Medicine Division, 2510 Kennedy Drive, Suite 117, Brooks Air Force Base, TX 78235–5119. Physiological training records at Air Force Physiological Training Units; individual physiological training records for non-aircrew personnel at consolidated flight record custodians at Air Force installations. Official mailing addresses are published as an appendix to the Air Force's compilation of systems of records notices. National Personnel Records Center, Military Personnel Records, 9700 Page Boulevard, St. Louis, MO 63132.'

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CATEGORIES OF RECORDS IN THE SYSTEM:

Delete first sentence.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

Delete entry and replace with '10 U.S.C. 8013, Secretary of the Air Force: Powers and duties; delegation by, as implemented by Air Force Instruction 11–403, Air Force Aerospace Physiological Training Program.'

PURPOSE(S):

Delete entry and replace with 'Authenticate type of training, location and trainees performance during course. Flight profiles (altitude chamber) and any reactions occurring during flight are maintained by each Physiological Training Unit for future authentication of training. Additional authentication is provided flight managers and scheduling officers and copies of flight profiles and reaction data are provided United States Air Force School of Aerospace Medicine for research. A compilation of select data is forwarded to appropriate Command Coordinator for Physiological Training for management purposes, to United States Air Force School of Aerospace Medicine, and Human System Center, Data Sciences Division for analysis and research, and to the Air Force Medical Operations Agency for management and research. Data for specific reactors to low pressure are handled as medical records with additional distribution to appropriate Major Air Command Surgeon for information and possible corrective action, to Armstrong Laboratory, Hyperbaric Medicine Division for research and analysis and to Headquarters Air Force Medical Operations Agency for policy/management/statistical and research analysis.'

* * * * *

RETRIEVABILITY:

Delete the words 'filed' and insert 'retrieved.'

SAFEGUARDS:

Delete entry and replace with 'Records are accessed by commanders of medical centers and hospitals and by person(s) responsible for servicing the record system in performance of their official duties and by authorized personnel who are properly screened and cleared for need-to-know. Records are stored in locked rooms and cabinets.'

RETENTION AND DISPOSAL:

Delete entry and replace with 'Chamber Flight Record at United States Air Force School of Aerospace Medicine retained until entered into computer files, until superseded, obsolete, or no longer needed for reference. Physiological Training Monthly Report (original) at Headquarters Air Force Medical Operations Agency is retained in office files until superseded, obsolete, no longer needed for reference, or on inactivation. Copies at locations are retained in office files until superseded, obsolete, no longer needed for reference, or on inactivation. Physiological Training Record are retained for 7 years; Individual Physiological Training Records for non-flying personnel retained as a part of individual medical record until member separates from active or Reserve duty. For flying personnel, record is retained in flight records and turned over to individual upon discharge, separation, or retirement.'

SYSTEM MANAGER(S) AND ADDRESS:

Delete entry and replace with 'Commander, Air Force Medical Operations Agency, 170 Luke Avenue,

Suite 400, Bolling Air Force Base, DC 20332–5113.'

NOTIFICATION PROCEDURE:

Delete entry and replace with 'Individuals seeking to determine whether this system of records contains information on themselves should address written inquiries to the Chief Aerospace Physiology, Air Force Medical Operations Agency, 170 Luke Avenue, Suite 400, Bolling Air Force Base, DC 20332–5113.

Students should provide full name, military status, approximate date and last location of training; officers and technicians assigned Air Force Aerospace Physiology Programs provide full name and location of last training.'

RECORD ACCESS PROCEDURES:

Delete entry and replace with 'Individuals seeking to access records about themselves contained in this system should address written requests to the Chief Aerospace Physiology, Air Force Medical Operations Agency, 170 Luke Avenue, Suite 400, Bolling Air Force Base, DC 20332–5113.

Students should provide full name, military status, approximate date and last location of training; officers and technicians assigned Air Force Aerospace Physiology Programs provide full name and location of last training. Requesters may visit Air Force Medical Service Center. Proof of identity is by government ID Card for active/retired, driver's license for others.'

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F161 AF SG A

SYSTEM NAME:

Air Force Aerospace Physiology Training Programs.

SYSTEM LOCATION:

Chamber Flight Records located at Human Systems Center, Data Sciences Branch, 2510 Kennedy Circle, Suite 3, Brooks Air Force Base, TX 78235–5199; Physiological Training monthly reports at each Air Force Physiological Training Unit; Headquarters Air Force Medical Operation Agency, 170 Luke Avenue, Suite 400, Bolling Air Force Base, DC 20332–5113; Medical records at Armstrong Laboratory, Aerospace Medicine Directorate, Hyperbaric Medicine Division, 2510 Kennedy Drive, Suite 117, Brooks Air Force Base, TX 78235–5119. Physiological training records at Air Force Physiological Training Units; individual physiological training records for non-aircrew personnel at consolidated flight record custodians at Air Force installations. Official mailing addresses are published as an appendix to the Air Force's compilation of systems of records notices. National Personnel Records Center, Military Personnel Records, 9700 Page Boulevard, St. Louis, MO 63132.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

All Aircrew and non-aircrew personnel required to fly on Air Force aircraft.

CATEGORIES OF RECORDS IN THE SYSTEM:

Contains data on attendance at formal training, type of course received, quality performance, training flight profiles, location of training, age, height, weight and sex of trainees.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

10 U.S.C. 8013, Secretary of the Air Force: Powers and duties; delegation by, as implemented by Air Force Instruction 11–403, Air Force Aerospace Physiological Training Program.

PURPOSE(S):

Authenticate type of training, location and trainees performance during course. Flight profiles (altitude chamber) and any reactions occurring during flight are maintained by each Physiological Training Unit for future authentication of training. Additional authentication is provided flight managers and scheduling officers and copies of flight profiles and reaction data are provided United States Air Force School of Aerospace Medicine for research. A compilation of select data is forwarded to appropriate Command Coordinator for Physiological Training for management purposes, to United States Air Force School of Aerospace Medicine, and Human System Center, Data Sciences Division for analysis and research, and to the Air Force Medical Operations Agency for management and research. Data for specific reactors to low pressure are handled as medical records with additional distribution to appropriate Major Air Command Surgeon for information and possible corrective action, to Armstrong Laboratory, Hyperbaric Medicine Division for research and analysis and to Headquarters Air Force Medical Operations Agency for policy/management/statistical and research analysis.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

In addition to those disclosures generally permitted under 5 U.S.C. 552a(b) of the Privacy Act, these records, or information contained therein, may specifically be disclosed outside the DOD as a routine use pursuant to 5 U.S.C. 552a(b)(3) as follows:

The 'Blanket Routine Uses' published at the beginning of the Air Force's compilation of systems of records notices apply to this system.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Record of training, records of individuals in a given class, altitude flight profiles, combined data of all individuals trained each month, and data on technicians providing the training are maintained in file folders, and in visible file cabinets.

RETRIEVABILITY:

Data relative to reactors to low pressure, management analysis procedures retrieved by Social Security Number. Authentication of training filed by name.

SAFEGUARDS:

Records are accessed by commanders of medical centers and hospitals and by person(s) responsible for servicing the record system in performance of their official duties and by authorized personnel who are properly screened and cleared for need-to-know. Records are stored in locked rooms and cabinets.

RETENTION AND DISPOSAL:

Chamber Flight Record at United States Air Force School of Aerospace Medicine retained until entered into computer files, until superseded, obsolete, or no longer needed for reference. Physiological Training Monthly Report (original) at Headquarters Air Force Medical Operations Agency is retained in office files until superseded, obsolete, no longer needed for reference, or on inactivation. Copies at locations are retained in office files until superseded, obsolete, no longer needed for reference, or on inactivation. Physiological Training Record are retained for 7 years; Individual Physiological Training Records for non-flying personnel retained as a part of individual medical record until member separates from active or Reserve duty. For flying personnel, record is retained in flight records and turned over to individual upon discharge, separation, or retirement.

SYSTEM MANAGER(S) AND ADDRESS:

Commander, Air Force Medical Operations Agency, 170 Luke Avenue, Suite 400, Bolling Air Force Base, DC 20332–5113.

NOTIFICATION PROCEDURE:

Individuals seeking to determine whether this system of records contains information on themselves should address written inquiries to the Chief Aerospace Physiology, Air Force Medical Operations Agency, 170 Luke Avenue, Suite 400, Bolling Air Force Base, DC 20332–5113.

Students should provide full name, military status, approximate date and last location of training; officers and technicians assigned Air Force Aerospace Physiology Programs provide full name and location of last training.

RECORD ACCESS PROCEDURES:

Individuals seeking to access records about themselves contained in this system should address written requests to the Chief Aerospace Physiology, Air Force Medical Operations Agency, 170 Luke Avenue, Suite 400, Bolling Air Force Base, DC 20332–5113.

Students should provide full name, military status, approximate date and last location of training; officers and technicians assigned Air Force Aerospace Physiology Programs provide full name and location of last training. Requesters may visit Air Force Medical Service Center. Proof of identity is by government ID Card for active/retired, driver's license for others.

CONTESTING RECORD PROCEDURES:

The Air Force rules for accessing records and for contesting contents and appealing initial agency determinations are published in Air Force Instruction 37–132; 32 CFR part 806b; or may be obtained from the system manager.

RECORD SOURCE CATEGORIES:

Physiological Training Unit (PTU).

EXEMPTIONS CLAIMED FOR THE SYSTEM:

None.

F161 AF SG B

SYSTEM NAME:

United States Air Force Compression Chamber Operation *(February 22, 1993, 58 FR 10460).*

CHANGES:

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SYSTEM LOCATION:

Delete entry and replace with 'Treatment records (original) retained in individual health record at United States Air Force hospitals; medical centers and clinics as part of health records or National Personnel Records Center, Civilian Personnel Records, 111 Winnebago Street, St. Louis, MO 63118; first copy retained at Armstrong Laboratory, Aerospace Medicine Directorate, Hyperbaric Medicine Division, 2510 Kennedy Circle, Suite 117, Brooks Air Force Base, TX 78235–5119; other copies at Air Force Medical Operations Agency; major command headquarters, and individual Physiological Training Units having compression therapy capability. Compression Chamber Reactor Case Report (original) at Air Force hospitals, medical centers and clinics as part of health record or at the National Personnel Records Center. First copy retained at Armstrong Laboratory. Other copies at Headquarters Air Force Medical Operations Agency, major command headquarters, and individual Physiological Training Unit having compression therapy capabilities. Oxygen Sensitivity Tolerance/Pressure Test at National Personnel Records Center, Air Force Hospitals, medical centers and clinics, as part of health records. Official mailing addresses are published as an appendix to the Air Force's compilation of record systems notices.'

* * * * *

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

Delete entry and replace with '10 U.S.C. 8013, Secretary of the Air Force: Powers and duties; delegation by; 10 U.S.C. 55, Medical and Dental Care, as implemented by Air Force Instruction 48–104, Aerospace Medicine.'

PURPOSE(S):

Delete entry and replace with 'Provide an exact record for a patient treated by compression therapy and documents reactions of the patient's response to high pressure. Protects the patient by insuring that overexposure to high pressure does not occur.

Records are maintained on persons performing treatments because they are exposed to the same treatment profiles as their patients and to insure their capability of performing treatment and to determine in advance that they are not physiologically susceptible to potential hazards of treatment.

Used for research and statistical analysis, and management effectiveness by the Air Force Medical Operations Agency.

Records maintained on technicians/officers conducting procedures are maintained at treatment site to insure overexposure to high pressure does not occur and to determine professional adequacy to participate in treatment dives.'

* * * * *

RETRIEVABILITY:

Delete entry and replace with 'Retrieved by name.'

SAFEGUARDS:

Delete entry and replace with 'Records are accessed by commanders of medical centers and hospitals and by person(s) responsible for servicing the record system in performance of their official duties and by authorized personnel who are properly screened and cleared for need-to-know. Records are stored in locked rooms and cabinets.'

RETENTION AND DISPOSAL:

Delete entry and replace with 'Treatment Records (original) retained in individual health record for fifty years after date of latest document and then destroyed. First copy and other copies at Armstrong Laboratory, Air Force Medical Operations Agency and major commands are retained in office files until superseded, obsolete, no longer needed for reference, or on inactivation, then destroyed. Copies at Physiological Training Units are destroyed after 3 years; Compression Chamber Operation Record at Physiological Training Units are retained in office files until superseded, obsolete, no longer needed for reference, or on inactivation, then destroyed. Compression Chamber Reaction Case Report (original) retained in individual health record for fifty years after date of latest document, then destroyed. First copy at Armstrong Laboratory and other copies at Headquarters Air Force Medical Operations Agency and major commands are retained in office files until superseded, obsolete, no longer needed for reference, or on inactivation, then destroyed. Copies at Physiological Training Units retained in office files until superseded, obsolete, no longer needed for reference, or on inactivation, then destroyed. Oxygen Sensitivity Tolerance/Pressure Test retained in individual health record for fifty years after date of latest document, then destroyed. All records are destroyed by tearing into pieces, shredding, pulping, macerating or burning.'

SYSTEM MANAGER(S) AND ADDRESS:

Delete entry and replace with 'Commander, Headquarters Air Force Medical Operation Agency, 170 Luke Avenue, Suite 400, Bolling Air Force Base, DC 20332–5113.'

NOTIFICATION PROCEDURE:

Delete entry and replace with 'Individuals seeking to determine whether this system of records contains information on themselves should address written inquiries to Commander, Headquarters Air Force Medical Operation Agency, 170 Luke

Avenue, Suite 400, Bolling Air Force Base, DC 20332–5113.

Required information for military/ex-military is full name, Social Security number; civilian should provide name, Social Security Number, location of treatment, and approximate date of treatment. Requester may visit system locations. Proof of identity is by government ID card for active/retired military, driver's license for civilians.'

RECORD ACCESS PROCEDURES:

Delete entry and replace with 'Individuals seeking to access records about themselves contained in this system should address written requests to Commander Headquarters, Air Force Medical Operation Agency, 170 Luke Avenue, Suite 400, Bolling Air Force Base, DC 20332–5113; Commander, Air Force Health Care Support Agency, Brooks Air Force Base, TX 78235–5000.

Requester may visit system locations. Proof of identity is by government ID card for active/retired military, driver's license for civilians.'

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F161 AF SG B

SYSTEM NAME:

Compression Chamber Operation.

SYSTEM LOCATION:

Treatment records (original) retained in individual health record at United States Air Force hospitals; medical centers and clinics as part of health records or National Personnel Records Center, Civilian Personnel Records, 111 Winnebago Street, St. Louis, MO 63118; first copy retained at Armstrong Laboratory, Aerospace Medicine Directorate, Hyperbaric Medicine Division, 2510 Kennedy Circle, Suite 117, Brooks Air Force Base, TX 78235–5119; other copies at Air Force Medical Operations Agency; major command headquarters, and individual Physiological Training Units having compression therapy capability. Compression Chamber Reactor Case Report (original) at Air Force hospitals, medical centers and clinics as part of health record or at the National Personnel Records Center. First copy retained at Armstrong Laboratory. Other copies at Headquarters Air Force Medical Operations Agency, major command headquarters, and individual Physiological Training Unit having compression therapy capabilities. Oxygen Sensitivity Tolerance/Pressure Test at National Personnel Records Center, Air Force Hospitals, medical centers and clinics, as part of health records. Official mailing addresses are published as an appendix to the Air Force's compilation of record systems notices.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Officers/technicians performing treatments (normally medical doctors, aerospace physiologists/physiological training technicians); patients who are Active duty military personnel, retired Air Force military personnel, dependents of military personnel, dependents of retired military and civilians treated on an emergency basis.

CATEGORIES OF RECORDS IN THE SYSTEM:

Treatment records of patient and records of personnel conducting treatment. Records of exposure to high pressure profiles are maintained for patient and personnel conducting treatment. Records of training dives are maintained on officers and technicians performing treatment dives as well as their physical capability/tolerance to perform in subsequent treatment dives/procedures.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

10 U.S.C. 8013, Secretary of the Air Force: Powers and duties; delegation by; 10 U.S.C. 55, Medical and Dental Care, as implemented by Air Force Instruction 48–104, Aerospace Medicine.

PURPOSE(S):

Provide an exact record for a patient treated by compression therapy and documents reactions of the patient's response to high pressure. Protects the patient by insuring that overexposure to high pressure does not occur.

Records are maintained on persons performing treatments because they are exposed to the same treatment profiles as their patients and to insure their capability of performing treatment and to determine in advance that they are not physiologically susceptible to potential hazards of treatment.

Used for research and statistical analysis, and management effectiveness by the Air Force Medical Operations Agency.

Records maintained on technicians/officers conducting procedures are maintained at treatment site to insure overexposure to high pressure does not occur and to determine professional adequacy to participate in treatment dives.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

In addition to those disclosures generally permitted under 5 U.S.C. 552a(b) of the Privacy Act, these records, or information contained therein, may specifically be disclosed outside the DOD as a routine use pursuant to 5 U.S.C. 552a(b)(3) as follows:

The 'Blanket Routine Uses' published at the beginning of the Air Force's compilation of systems of records notices apply to this system.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Maintained in file folders and visible file binders/cabinets.

RETRIEVABILITY:

Retrieved by name.

SAFEGUARDS:

Records are accessed by commanders of medical centers and hospitals and by person(s) responsible for servicing the record system in performance of their official duties and by authorized personnel who are properly screened and cleared for need-to-know. Records are stored in locked rooms and cabinets.

RETENTION AND DISPOSAL:

Treatment Records (original) retained in individual health record for fifty years after date of latest document and then destroyed. First copy and other copies at Armstrong Laboratory, Air Force Medical Operations Agency and major commands are retained in office files until superseded, obsolete, no longer needed for reference, or on inactivation, then destroyed. Copies at Physiological Training Units are destroyed after 3 years; Compression Chamber Operation Record at Physiological Training Units are retained in office files until superseded, obsolete, no longer needed for reference, or on inactivation, then destroyed. Compression Chamber Reaction Case Report (original) retained in individual health record for fifty years after date of latest document, then destroyed. First copy at Armstrong Laboratory and other copies at Headquarters Air Force Medical Operations Agency and major commands are retained in office files until superseded, obsolete, no longer needed for reference, or on inactivation, then destroyed. Copies at Physiological Training Units retained in office files until superseded, obsolete, no longer needed for reference, or on inactivation, then destroyed. Oxygen Sensitivity Tolerance/Pressure Test retained in individual health record for fifty years after date of latest document, then destroyed. All records are destroyed by tearing into pieces, shredding, pulping, macerating or burning.

SYSTEM MANAGER(S) AND ADDRESS:

Commander, Headquarters Air Force Medical Operation Agency, 170 Luke Avenue, Suite 400, Bolling Air Force Base, DC 20332–5113.

NOTIFICATION PROCEDURE:

Individuals seeking to determine whether this system of records contains information on themselves should address written inquiries to Commander, Headquarters Air Force Medical Operation Agency, 170 Luke Avenue, Suite 400, Bolling Air Force Base, DC 20332–5113.

Required information for military/ex-military is full name, Social Security number; civilian should provide name, Social Security Number, location of treatment, and approximate date of treatment. Requester may visit system locations. Proof of identity is by government ID card for active/retired military, driver's license for civilians.

RECORD ACCESS PROCEDURES:

Individuals seeking to access records about themselves contained in this system should address written requests to Commander Headquarters, Air Force Medical Operation Agency, 170 Luke Avenue, Suite 400, Bolling Air Force Base, DC 20332–5113; Commander, Air Force Health Care Support Agency, Brooks Air Force Base, TX 78235–5000.

Requester may visit system locations. Proof of identity is by government ID card for active/retired military, driver's license for civilians.

CONTESTING RECORD PROCEDURES:

The Air Force rules for accessing records and for contesting contents and appealing initial agency determinations are published in Air Force Instruction 37–132; 32 CFR part 806b; or may be obtained from the system manager.

RECORD SOURCE CATEGORIES:

Physicians regarding diagnosis/treatment.

EXEMPTIONS CLAIMED FOR THE SYSTEM:

None.

F178 AFCC A

SYSTEM NAME:

Center Automated Manpower and Update System (CAMPUS) *(February 22, 1993, 58 FR 10496).*

CHANGES:

SYSTEM IDENTIFIER:

Change system identifier to 'F178 AFC4A A.'

* * * * *

SYSTEM LOCATION:

Delete entry and replace with 'Standard Systems Center (SSC), 201 E. Moore Drive, Maxwell Air Force Base, Gunther Annex, AL 36114–3005.'

* * * * *

RETRIEVABILITY:

Delete entry and replace with 'Retrieved by Social Security Number.'

SAFEGUARDS:

Records are accessed by person(s) responsible for servicing the record system in performance of their official duties and by authorized personnel who are properly screened and cleared for need-to-know. Records are stored in locked rooms and cabinets. Those in computer storage devices are protected by computer system software.'

* * * * *

SYSTEM MANAGER(S) AND ADDRESS:

Delete entry and replace with 'Commander, Standard Systems Center (SSC), 201 E. Moore Drive, Maxwell Air Force Base, Gunther Annex, AL 36114–3005.'

NOTIFICATION PROCEDURE:

Delete entry and replace with 'Individuals seeking to determine whether this system of records contains information on themselves should address written inquiries to the Commander, Standard Systems Center (SSC), 201 E. Moore Drive, Maxwell Air Force Base, Gunther Annex, AL 36114–3005.'

RECORD ACCESS PROCEDURES:

Delete entry and replace with 'Individuals seeking to access records about themselves contained in this system should address written requests to the Commander, Standard Systems Center (SSC), 201 E. Moore Drive, Maxwell Air Force Base, Gunther Annex, AL 36114–3005.'

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F178 AFC4A A

SYSTEM NAME:

Center Automated Manpower and Update System (CAMPUS).

SYSTEM LOCATION:

Standard Systems Center (SSC), 201 E. Moore Drive, Maxwell Air Force Base, Gunther Annex, AL 36114–3005.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Air Force active duty military personnel and civilian employees assigned to the SSC.

CATEGORIES OF RECORDS IN THE SYSTEM:

CAMPUS records contain data on SSC personnel nonavailable time (time in man-hours chargeable as SSC overhead for purposes of total man-hour accounting), personnel available time (time chargeable against a specific human resource package) and workload tracking data (data on project or task). Included in nonavailable time are leave, training, and all activities not related to the SSC's primary mission. Available time includes administrative duties, management/supervision functions, time spent in general support areas and time devoted to developing new and/or maintaining existing computer software. Workload tracking includes data on pending, active, and completed activities as to estimated/actual resources required, estimated/actual dates, and identification data.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

10 U.S.C. 8013, Secretary of the Air Force: Powers and duties; delegation by; and E.O. 9397.

PURPOSE(S):

CAMPUS provides information to SSC management personnel about manpower utilization within the organization. Specific uses of the system by all management levels include monitoring of manpower resources expended on ADP projects, validating and defending the SSC manpower posture with workload and man-hour expenditure data, and distributing workloads between and within the SSC directorates.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

In addition to those disclosures generally permitted under 5 U.S.C. 552a(b) of the Privacy Act, these records, or information contained therein, may specifically be disclosed outside the DOD as a routine use pursuant to 5 U.S.C. 552a(b)(3) as follows:

The 'Blanket Routine Uses' published at the beginning of the Air Force's compilation of systems of records notices apply to this system.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Maintained on computer and computer output products.

RETRIEVABILITY:

Retrieved by Social Security Number.

SAFEGUARDS:

Records are accessed by person(s) responsible for servicing the record system in performance of their official duties and by authorized personnel who are properly screened and cleared for

need-to-know. Records are stored in locked rooms and cabinets. Those in computer storage devices are protected by computer system software.

RETENTION AND DISPOSAL:

Hard-copy listings are retained in office files until superseded, obsolete, or no longer needed, then destroyed by tearing into pieces, shredding, pulping, macerating, or burning.

SYSTEM MANAGER(S) AND ADDRESS:

Commander, Standard Systems Center (SSC), 201 E. Moore Drive, Maxwell Air Force Base, Gunther Annex, AL 36114–3005.

NOTIFICATION PROCEDURE:

Individuals seeking to determine whether this system of records contains information on themselves should address written inquiries to the Commander, Standard Systems Center (SSC), 201 E. Moore Drive, Maxwell Air Force Base, Gunther Annex, AL 36114–3005.

RECORD ACCESS PROCEDURES:

Individuals seeking to access records about themselves contained in this system should address written requests to the Commander, Standard Systems Center (SSC), 201 E. Moore Drive, Maxwell Air Force Base, Gunther Annex, AL 36114–3005.

CONTESTING RECORD PROCEDURES:

The Air Force rules for accessing records and for contesting contents and appealing initial agency determinations are published in Air Force Instruction 37–132; 32 CFR part 806b; or may be obtained from the system manager.

RECORD SOURCE CATEGORIES:

Information for CAMPUS is obtained from the individuals assigned to the SSC.

EXEMPTIONS CLAIMED FOR THE SYSTEM:

None.

F200 AFIS B

SYSTEM NAME:

DIA Program for Foreign Intelligence Collection *(February 22, 1993, 58 FR 10501).*

CHANGES:

SYSTEM IDENTIFIER:

Change system identifier to 'F200 AFIC A.'

* * * * *

SYSTEM LOCATION:

Delete entry and replace with 'Headquarters 696 Inspector General, Andrews Air Force Base, MD 20331–6500, and subordinate units. Official mailing addresses are published as an appendix to the Air Force's compilation of systems of records notices.'

* * * * *

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

Delete entry and replace with 'In addition to those disclosures generally permitted under 5 U.S.C. 552a(b) of the Privacy Act, these records, or information contained therein, may specifically be disclosed outside the DOD as a routine use pursuant to 5 U.S.C. 552a(b)(3) as follows:

The 'Blanket Routine Uses' published at the beginning of the Air Force's compilation of systems of records notices apply to this system.'

* * * * *

SYSTEM MANAGER(S) AND ADDRESS:

Delete entry and replace with 'Headquarters 696 Inspector General/DOO, Andrews Air Force Base, MD 20331–6500, Submanager, Commander, Detachment 2, 696 IG, Wright-Patterson Air Force Base, OH 45433–5607.'

NOTIFICATION PROCEDURE:

Delete address and replace with 'Headquarters 696 Inspector General/DOO, Andrews Air Force Base, MD 20331–6500, or Submanager, Commander, Detachment 2, 696 IG, Wright-Patterson Air Force Base, OH 45433–5607.'

RECORD ACCESS PROCEDURES:

Delete address and replace with 'Headquarters 696 Inspector General/DOO, Andrews Air Force Base, MD 20331–6500, or Submanager, Commander, Detachment 2, 696 IG, Wright-Patterson Air Force Base, OH 45433–5607.'

* * * * *

F200 AFIC A

SYSTEM NAME:

DIA Program for Foreign Intelligence Collection.

SYSTEM LOCATION:

Headquarters 696 Inspector General, Andrews Air Force Base, MD 20331–6500, and subordinate units. Official mailing addresses are published as an appendix to the Air Force's compilation of systems of records notices.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Air Force Reserve personnel, retired Air Force military personnel, foreign nationals residing in the United States, U.S. Citizens, and foreign nationals overseas who are sources or support assets for foreign intelligence collection operations.

CATEGORIES OF RECORDS IN THE SYSTEM:

Biographic data and records incidental to foreign intelligence collection operations.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

National Security Act of 1947, Pub. L. 257, July 26, 1947 (61 Stat 495); as implemented by Air Force Regulation 200–3, The Medical Intelligence Program.

PURPOSE(S):

Routine internal reference relative to use or possible use in foreign intelligence collection operations.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

In addition to those disclosures generally permitted under 5 U.S.C. 552a(b) of the Privacy Act, these records, or information contained therein, may specifically be disclosed outside the DOD as a routine use pursuant to 5 U.S.C. 552a(b)(3) as follows:

The 'Blanket Routine Uses' published at the beginning of the Air Force's compilation of systems of records notices apply to this system.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Maintained in file folders and note books/binders, and on computer paper printouts and roll microfilm.

RETRIEVABILITY:

Retrieved by name and National File Number.

SAFEGUARDS:

Records are accessed by custodian of the record system and by person(s) responsible for servicing the record system in performance of their official duties who are properly screened and cleared for need-to-know. Records are stored in security file containers/cabinets and safes.

RETENTION AND DISPOSAL:

Prior to destruction, files are screened, purged of extraneous material, and microfilmed. Microfilm retained indefinitely.

SYSTEM MANAGER(S) AND ADDRESS:

Headquarters 696 Inspector General/DOO, Andrews Air Force Base, MD 20331–6500, Submanager, Commander, Detachment 2, 696 IG, Wright-Patterson Air Force Base, OH 45433–5607.

NOTIFICATION PROCEDURE:

Individuals seeking to determine whether this system of records contains information on themselves should address written inquiries to Headquarters 696 Inspector General/DOO, Andrews Air Force Base, MD 20331–6500, or Submanager, Commander, Detachment 2, 696 IG, Wright-Patterson Air Force Base, OH 45433–5607.

RECORD ACCESS PROCEDURES:

Individuals seeking to access records about themselves contained in this system should address written requests to Headquarters 696 Inspector General/DOO, Andrews Air Force Base, MD 20331–6500, or Submanager, Commander, Detachment 2, 696 IG, Wright-Patterson Air Force Base, OH 45433–5607.

CONTESTING RECORD PROCEDURES:

The Air Force rules for accessing records and for contesting contents and appealing initial agency determinations are published in Air Force Instruction 37–132; 32 CFR part 806b; or may be obtained from the system manager.

RECORD SOURCE CATEGORIES:

Information obtained from biographical data and records incident to foreign intelligence collection operations.

EXEMPTIONS CLAIMED FOR THE SYSTEM:

None.

[FR Doc. 93-28650 Filed 11-22-93;8:45am]
BILLING CODE 5000-04F

Department of the Army

Office of the Secretary; Supplemental Environmental Assessment for Realignment Actions at Letterkenny Army Depot, Pennsylvania

AGENCY: Department of Defense, United States Army.

ACTION: Finding of No Significant Impact.

SUMMARY: The proposed action implements the July 1993 Defense Base Closure and Realignment Commission's (BRAC 93) decision to realign administrative and maintenance workloads at Letterkenny Army Depot (LEAD). The administrative realignment, which affirmed the 1991 Base Closure and Realignment Commission's (BRAC 91) decision, transfers Headquarters, U.S. Army Depot System Command (DESCOM) from LEAD to Rock Island Arsenal, Illinois. Systems Integration and Management Activity-East (SIMA-E) will not transfer from LEAD as originally recommended by BRAC 91. In addition, the artillery maintenance workload will remain at LEAD.

Maintenance realignments, including all applicable secondary items, subassemblies and peripherals, are occurring to consolidate workloads among Army depots. These realignments involve the following:

—The transfer of tactical missile maintenance workloads from contractor facilities, Anniston Army Depot, Tobyhanna Army Depot (AN/TSQ–73 Air Defense Command and Control System), Red River Army Depot, and Navy, Marine and Air Force facilities to LEAD.

—Tactical missile maintenance will also transfer from various contractor sites.

—The retention of the artillery maintenance workload at LEAD.

—The realignment of the Firefinder radar maintenance workload from Sacramento Army Depot (SAAD) to LEAD. The workload competition was won by McClellan Air Logistics Center. However, LEAD is protesting the award. Firefinder will be referenced in all LEAD publications until the protest is settled.

The overall effect of the realignments described above (with the exception of the Firefinder radar maintenance) will be a net gain of approximately 126 civilian personnel at LEAD. Should LEAD be successful in the protest, an additional 157 work-years for LEAD would result.

Alternatives considered in the Supplemental Environmental Assessment (SEA) include the following:

—The Preferred Alternative, which would transfer workload into renovated and existing facilities.

—Alternative 1, which would transfer workload into new and existing facilities.

—Alternative 2, the No-Action Alternative, which provides the baseline at LEAD against which the other alternatives can be compared.

The Preferred Alternative would not require building construction at LEAD, and would require only internal renovations to existing buildings. The workload to be transferred to LEAD is the same or similar to maintenance work already conducted at LEAD. The overall result will be a slight increase in positions at the installation as the maintenance workload increases. This increase would affect water and energy use, waste water flows, air emissions, and municipal, solid and hazardous waste generation. Neither the resources used or waste streams produced would have a significant impact on the environment. Biological, physical, and cultural resources would not be affected by this action since existing buildings to be renovated and used for maintenance activities are located in developed or otherwise disturbed areas.

The proposed realignments are expected to have an insignificant effect on the socioeconomic environment, including total sales, employment, population and income.

Based on the environmental impact analyses found in the August 1992 Environmental Assessment and supplemented by this EA, which is hereby incorporated into this Finding of No Significant Impact (FNSI), it has been determined that implementation of the proposed action would not have significant individual or cumulative impacts on the quality of the natural or human environment. Because there would be no significant environmental impacts resulting from implementation of the proposed action, an Environmental Impact Statement is not required and will not be prepared.

DATES: Comments must be received within 30 days from the publishing date of this notice.

ADDRESSES: Persons wishing to comment may obtain a copy of the supplemental and original EA's or inquire into this FNSI by writing to the Public Affairs Officer, Letterkenny Army Depot, ATTN: SDSLE–CA, Chambersburg, Pennsylvania.

FOR FURTHER INFORMATION CONTACT: Questions regarding this FNSI may be directed to the Public Affairs Officer at (717) 267–5102.

Lewis D. Walker,

Deputy Assistant Secretary of the Army, (Environment, Safety & Occupational Health OASA (IL&E).

[FR Doc. 93–28692 Filed 11–22–93; 8:45 am]
BILLING CODE 3710–08–M

Intent to Prepare a Draft Environmental Impact Statement (DEIS) for a Flood Control Project on the White River in Indianapolis, Marion County, IN

AGENCY: U.S. Army Corps of Engineers, Louisville District, DOD.

ACTION: Notice.

SUMMARY: The U.S. Army Engineer District, Louisville Corps of Engineers is presently undertaking the preparation of a DEIS for a flood control project along reaches of the White River in northern Indianapolis, Marion County, Indiana. The primary purpose of this study is to investigate the feasibility and the extent of Federal interest in providing a

solution to local flooding problems along the White River. This feasibility study is conducted under the authority of a resolution adopted on May 6, 1958 by the Committee on Public Works of the United States Senate and by continuing appropriations. The City of Indianapolis, Department of Public Works, in a letter dated October 2, 1992, stated that the city was interested in cost sharing with the Corps of Engineers a feasibility study of a project in Indianapolis. A cost sharing agreement was entered into on March 4, 1993.

ADDRESSES: U.S. Army Engineer District, Louisville, Corps of Engineers, CEORL–PD–R, P.O. Box 59, Louisville, Kentucky 40201–0059.

FOR FURTHER INFORMATION CONTACT: Questions or comments concerning the preparation of this DEIS should be addressed to Mr. Van Shipley at (502) 582–5774.

SUPPLEMENTARY INFORMATION: The Louisville District completed a Reconnaissance report in July 1992, which concluded that there appears to be economically feasible and environmentally sustainable solutions to the flooding problems present along reaches of the White River in northern Indianapolis, Marion County, Indiana. The study area includes approximately 13.5 miles of the White River extending from the I–465 crossing of the river in northern Indianapolis downstream to the I–65 crossing of the river. The proposed reasonable alternatives to prevent impacts of flooding along the White River are to rehabilitate existing levees, raise existing levees or construct new levees and pump plants. The District's scoping process has involved meetings with local groups and state and Federal agencies. Public workshops were held in Indianapolis within the project area on May 17 and June 8, 1993 at the Broad Ripple High School and Rocky Ripple Town Hall, respectively. The major significant issues brought up during the workshops that will be analyzed in depth in the DEIS are:

1. Removal of trees growing on the riverside slope of the existing levees be minimized.
2. Home relocation be minimized.
3. Recreational facilities may not be proper for all reaches considered under this flood control study.

The White River is a tributary to the Wabash River with the confluence occurring along the Gibson and Knox County borders, adjacent to the city of Mt. Carmel, Illinois in southwestern Indiana. The drainage area of the White River is 6,500 square miles. The White River lies entirely within the state of Indiana and extends generally in a north-eastwardly direction to its headwaters which rise in Randolph County along the Ohio border.

Subsequent to the 1913 flood in the Wabash River Basin, local interests developed a comprehensive plan to protect Indianapolis against a recurrence of that flood event. Implementation of the plan began in 1915 by the City of Indianapolis and later by the Works Progress Administration, and all work accomplished since has been in general accordance with the adopted comprehensive plan. Both structural and non-structural flood protection measures are in place in Indianapolis. The structural projects include reservoirs, levees, floodwalls, diversions and channel improvements. The nonstructural measures include state and local building ordinances and zoning as provided under the mergence phase of the National Flood Insurance Program. The most predominant form of existing flood protection along the White River primary study area is levees, however, the level of protection afforded by them, and their current conditions, are highly variable from location to location. The levees were built over a considerable time period, by different agencies and/or by private interests, and therefore differ considerably with regard to their structural condition.

The endangered species of major concern for this study if the Indiana bat. However, if removal of trees are minimized endangered species consultation should not be necessary for the proposed project. Other environmental requirements are in regard to the Clear Water Act. If required, a Section 404(b)(1) evaluation will be prepared as an appendix to the DEIS. A Section 401 State Water Quality Certification will be requested at that time. The Section 402 National Pollutant Discharge Elimination System, Pollution Prevention Plan and Notice of Intent under the State of Indiana General Permit will be prepared and submitted to the State of Indiana just prior to construction.

The public involvement will include meetings and close coordination with interested private individuals and organizations, as well as concerned Federal, state and local agencies. A public notice requesting comments on the proposed project and DEIS will be provided to appropriate agencies and the public through printed media and mailings. A scoping meeting is tentatively planned for mid January to early February 1994. The Louisville District invites potentially affected Federal, state and local agencies, and other interested organizations and parties to participate in this study. Agencies that are currently involved in the feasibility study and EIS process include, but are not limited to the U.S. Environmental Protection Agency, U.S. Fish and Wildlife Service, U.S. Soil Conservation Service, City of Indianapolis and Marion County.

The DEIS is tentatively scheduled to be available for public review in the spring of 1995.

Kenneth L. Denton,

Army Federal Register Liaison Officer.

[FR Doc. 93–28643 Filed 11–22–93; 8:45 am]

BILLING CODE 3710–02–M

Notice of Availability, Final, Environmental Impact Statement Addressing the Relocation of the Woodbridge Research Facility Electromagnetic Pulse Simulators

AGENCY: Department of the Army, DoD.

ACTION: Notice of availability.

SUMMARY: The Department of Army announces the completion of a Final EIS addressing the proposed action to relocate existing inactive EMP simulators from the Woodbridge Research Facility, Woodbridge, Virginia, to construct a new simulator, the Vertical EMP Simulator II (VEMPS II), and to operate them at a new location. (The Notice of Intent and the Notice of Availability of the Draft EIS for this action were previously announced in 54 F.R., No. 207, P. 43847 and 57 F.R., No. 201, P. 47463 respectively.)

The Draft EIS provided detailed information gathered from six candidate relocation sites. These included one site at Dugway Proving Ground, Utah, four sites at White Sands Missile Range, New Mexico, and one site at Yuma Proving Ground, Arizona. Alternatives considered in the Draft EIS included:

—Alternative 1, the proposed action, to relocate and operate the simulators at one of the six candidate relocation sites;
—Alternative 2, to conduct such testing by other means of simulation;
—Alternative 3, to have other military, Federal departments or contractors conduct such testing;
—Alternative 4, to cease type of testing (do not relocate the simulators, the no-action alternative).

The Draft EIS did not identify a preferred relocation site. After the completion of the Draft EIS the Army determined its preferred site to be the Orogrande site in the southeast corner of the White Sands Missile Range, for operational reasons.

The Final EIS incorporates all responses to the Draft EIS, including those received from Federal, state and local agencies, private citizens, and civic and environmental organizations. It also includes additional specific information developed for the preferred site from consultations held with the U.S. Fish and Wildlife Service, in accordance with the Endangered Species Act, and the New Mexico State Historic Preservation Office, in accordance with the National Historic Preservation Act. The Final EIS evaluates the candidate sites and identifies the Orogrande site as the environmentally preferred site.

LEAD AGENCY: U.S. Army Research Laboratory.

ADDRESSES: All interested parties may obtain a copy of the Final EIS by writing to U.S. Army Research Laboratory, Public Affairs Office, 2800 Powder Mill Road, Adelphi, Maryland 20783–1145.

FOR FURTHER INFORMATION CONTACT: Questions regarding this Notice of Availability action may be directed to Mr. David Davison by calling (301) 394–3590.

Lewis D. Walker,

Deputy Assistant Secretary of the Army, (Environment, Safety and Occupational Health) OASA (I,L&E).

[FR Doc. 93–28654 Filed 11–22–93; 8:45 am]

BILLING CODE 3710–08–M

Defense Nuclear Agency

Privacy Act of 1974; Delete and Amend Record Systems

AGENCY: Defense Nuclear Agency, DOD.

ACTION: Delete and amend record systems.

SUMMARY: The Defense Nuclear Agency proposes to delete two and amend four existing systems of records in its inventory of record systems subject to the Privacy Act of 1974, (5 U.S.C. 552a), as amended.

DATES: The amendments will be effective on December 23, 1993, unless comments are received that would result in a contrary determination.

ADDRESSES: Send comments to General Counsel, Defense Nuclear Agency, 6801 Telegraph Road, Alexandria, VA 22310–3398.

FOR FURTHER INFORMATION CONTACT: Ms. Sandy Barker at (703) 325–7681.

SUPPLEMENTARY INFORMATION: The Defense Nuclear Agency systems of records notices for records systems subject to the Privacy Act of 1974, (5 U.S.C. 552a), as amended, have been published in the **Federal Register** and are available from the above address.

These changes are necessary due to the transfer (effective October 1, 1993) of host management of the Armed Forces Radiobiology Institute (AFRRI) from the Defense Nuclear Agency (DNA) to the Uniformed Services University of the Health Sciences (USUHS), and DNA's recordkeeping responsibility for personnel-related records of the On Site Inspection Agency. Therefore, any reference to AFRRI has been deleted from the following systems of record notices which are published below in their entirety, as amended.

The amendments are not within the purview of subsection (r) of the Privacy Act of 1974 (5 U.S.C. 552a), as amended, which requires the submission of altered systems reports.

Dated: November 18, 1993.

Patricia L. Toppings,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

DELETIONS

HDNA 003

SYSTEM NAME:

Drug-Free Workplace Files *(February 22, 1993, 58 FR 10550).*

Reason: This system is currently covered under OPM/GOVT–10 *(August 10, 1992, 57 FR 35722)* and a separate system notice is no longer needed.

HDNA 009

SYSTEM NAME:

Personnel Radiation Exposure Records *(February 22, 1993, 58 FR 10555).*

Reason: This system has been transferred with the host management of the Armed Forces Radiobiology Research Institute from the Defense Nuclear Agency to the Uniformed Services University of the Health Sciences (USUHS). Washington Headquarters Service has incorporated this system into WUSU11, USUHS Radiation Dosimetry Records *(February 22, 1993, 58 FR 10928).*

AMENDMENTS

HDNA 001

SYSTEM NAME:

Employee Assistance Program.

SYSTEM LOCATION:

The Occupational Health Unit, Headquarters, Defense Nuclear Agency, 6801 Telegraph Road, Alexandria, VA 22310–3398; the Civilian Personnel Office, Building 20203A, Kirtland Air Force Base, NM 87115–5000; and the Civilian Personnel Office, On Site Inspection Agency, Dulles International Airport, Washington, DC 20041–0498.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

All civilian employees in appropriated and non-appropriated fund activities who are referred by management for, or voluntarily request, counseling assistance.

CATEGORIES OF RECORDS IN THE SYSTEM:

Case records on employees which are maintained by counselors, supervisors, and civilian personnel offices, that consist of information on condition, current status, and progress of employees or dependents who have alcohol, drug, or emotional problems (referrals only).

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

Drug Abuse Office and Treatment Act of 1972, as amended by Pub.L. 93–282 (21 U.S.C. 1175); Subchapter A of Chapter I, Title 42, Code of Federal Regulations; Chapter 43 of 5 U.S.C.; and E.O. 9397.

PURPOSE(S):

For use by the Drug and Alcohol Abuse Coordinator in referring individuals for counseling and by management officials for follow-up actions.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

In addition to those disclosures generally permitted under 5 U.S.C. 552a(b) of the Privacy Act, these records or information contained therein may specifically be disclosed outside the DoD as a routine use pursuant to 5 U.S.C. 552a(b)(3) as follows:

In order to comply with provisions of 42 U.S.C. 290dd–3 and 290ee–3, the DNA 'Blanket Routine Uses' do not apply to this system of records.

Records in this system may not be disclosed without the prior written consent of such patient, unless the disclosure would be:

To medical personnel to the extent necessary to meet a bona fide medical emergency.

To qualified personnel for the purpose of conducting scientific research, management audits, financial audits, or program evaluation, but such personnel may not identify, directly or indirectly, any individual patient in any report of such research, audit, or evaluation, or otherwise disclose patient identities in any manner; and

If authorized by an appropriate order of a court of competent jurisdiction

granted after application showing good cause therefor.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Case records are stored in paper file folders.

RETRIEVABILITY:

Retrieved by the individuals Social Security Number.

SAFEGUARDS:

Buildings are protected by security guards and an intrusion alarm system. Records are maintained in locked security containers accessible only to personnel who are properly screened, cleared and trained.

RETENTION AND DISPOSAL:

Records are purged of identifying information within five years after termination of counseling or destroyed when they are no longer useful.

SYSTEM MANAGER(S) AND ADDRESS:

For Headquarters, Defense Nuclear Agency contact the Occupational Health Nurse, Occupational Health Unit, Headquarters, Defense Nuclear Agency, 6801 Telegraph Road, Alexandria, VA 22310–3398.

For Field Commands, DNA contact the Civilian Personnel Officer, Kirtland Air Force Base, NM 87115–5000,

NOTIFICATION PROCEDURE:

Individuals seeking to determine whether information about themselves is contained in this system of records should address written inquiries to the appropriate system manager.

The letter should contain the full name, Social Security Number, and signature of the requester and the approximate period of time, by date, during which the case record was developed.

RECORD ACCESS PROCEDURE:

Individuals seeking access to records about themselves contained in this system of records should address written inquiries to the appropriate system manager.

The letter should contain the full name, Social Security Number, and signature of the requester and the approximate period of time, by date, during which the case record was developed.

CONTESTING RECORD PROCEDURES:

The DNA rules for accessing records and for contesting contents and appealing initial agency determinations are published in DNA Instruction 5400.11A; 32 CFR part 318; or may be obtained from the system manager or the General Counsel, Headquarters, Defense Nuclear Agency, 6801 Telegraph Road, Alexandria, VA 22310–3398.

RECORD SOURCE CATEGORIES:

Counselors, other officials, individuals or practitioners, and other agencies both in and outside of Government.

EXEMPTIONS CLAIMED FOR THE SYSTEM:

None.

HNDA 002

SYSTEM NAME:

Employee Relations.

SYSTEM LOCATION:

Civilian Personnel Management Division, Manpower Management and Personnel, Command Services Directorate, Headquarters, Defense Nuclear Agency, 6801 Telegraph Road, Alexandria, VA 22310–3398; the Civilian Personnel Office, Building 20203A, Kirtland Air Force Base, NM 87115–5000; and the Civilian Personnel Office, On Site Inspection Agency, Dulles International Airport, Washington, DC 20041–0498.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Civilian employees and former employees paid from appropriated funds serving under career, career-conditional, temporary and excepted service appointments on whom suitability, discipline, grievance, and appeal records exist.

CATEGORIES OF RECORDS IN THE SYSTEM:

Documents and information pertaining to discipline, grievances, and appeals.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

5 U.S.C. 1302, 3301, 3302, 7301; E.O. 11222; E.O. 11557; E.O. 11491.

PURPOSE(S):

For use by agency officials and employees in the performance of their official duties related to management of civilian employees and the processing, administration and adjudication of discipline, grievances, suitability and appeals.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

In addition to those disclosures generally permitted under 5 U.S.C. 552a(b) of the Privacy Act, these records or information contained therein may specifically be disclosed outside the DoD as a routine use pursuant to 5 U.S.C. 552a(b)(3) as follows:

Appeals examiners of the Merit Systems Protection Board to adjudicate appeals.

The Comptroller General or his authorized representatives and the Attorney General of the United States or his authorized representatives in connection with grievances, disciplinary actions, suitability, and appeals, Federal Labor Relations officials in the performance of official duties.

The 'Blanket Routine Uses' published at the beginning of DNA's compilation of system of records notices apply to this system.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Records are stored in paper folders.

RETRIEVABILITY:

Retrieved alphabetically by last name of individual.

SAFEGUARDS:

Buildings are protected by security guards and an intrusion alarm system. Records are maintained in locked security containers in a locked room accessible only to personnel who are properly screened, cleared and trained.

RETENTION AND DISPOSAL:

Records are destroyed upon separation of the employee from the agency or in accordance with appropriate records disposal schedules.

SYSTEM MANAGER(S) AND ADDRESSES:

For Headquarters, Defense Nuclear Agency contact the Civilian Personnel Officer, Headquarters, Defense Nuclear Agency, 6801 Telegraph Road, Alexandria, VA 22310–3398.

For Field Commands, DNA contact the Civilian Personnel Officer, Kirtland Air Force Base, NM 87115–5000.

NOTIFICATION PROCEDURE:

Individuals seeking to determine whether information about themselves is contained in this system of records should address written inquiries to the appropriate system manager.

The letter should contain the full name and signature of the requester and the approximate period of time, by date during which the case record was developed.

RECORD ACCESS PROCEDURES:

Individuals seeking access to information about themselves contained in this system of records should address written inquiries to the appropriate system manager.

CONTESTING RECORD PROCEDURES:

The DNA rules for accessing records and for contesting contents and appealing initial agency determinations are published in DNA Instruction 5400.11A; 32 CFR part 318; or may be obtained from the system manager or the General Counsel, Headquarters, Defense Nuclear Agency, 6801 Telegraph Road, Alexandria, VA 22310–3398.

RECORD SOURCE CATEGORIES:

Supervisors or other appointed officials designated for this purpose.

EXEMPTIONS CLAIMED FOR THE SYSTEM:

None.

HDNA 005

SYSTEM NAME:

Manpower/Personnel Management System.

SYSTEM LOCATION:

Primary location is at the Manpower Management and Personnel, Command Services Directorate, Headquarters, Defense Nuclear Agency, 6801 Telegraph Road, Alexandria, VA 22310–3398.

Secondary locations exist at the following DNA subordinate commands: Field Command, Defense Nuclear Agency, Building 20364, Kirtland Air Force Base, NM 87115–5000;

Civilian Personnel Office, On Site Inspection Agency, Dulles International Airport, Washington, DC 20041–0498; and

the Defense Nuclear Agency, Las Vegas, NV 89193–8539.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Any individual, military or civilian, employed by DNA, and all On Site Inspection Agency civilian employees.

CATEGORIES OF RECORDS IN THE SYSTEM:

File contains the following information on all personnel assigned to DNA: Social Security Number; agency; employee name; birth date; veteran's preference; tenure group; service computation date; federal employees group life insurance; retirement code; nature of action code; effective date of action; position number; pay plan; occupation code; functional classification code; grade; step; pay basis; salary; supervisory position; location code/duty station; position occupied; work schedule; pay rate determinant; sex; citizen status; date entered present grade; date entered present step; separation date; reason for separation (quit code); cost center; academic discipline; career conditional appointment date (conversion to career); education level; degree date; purpose of training; type of training; source of training; special interest; direct cost; indirect cost; date of completion; on-duty hours; off-duty hours; JTD paragraph number; JTD line number; competitive level; military service retirement date; uniformed service; joint specialty officer; service position number; career status; officer evaluation report date (Army only); highest professional military education; rank; grade; status of incumbent in Personnel Reliability Program (PRP); date of latest PRP certification;' promotion sequence number; service commissioned. (military); service pay grande (rank); Agency sub-element code; submitting office number; retired military code; bureau; unit identification code; program element code; civil function code; guard/reserve technician; appropriation code; active/inactive strength designation; work center code; projected vacancy date; targeted grade; position title; date of last equivalent increase; fair labor standards act designator; health benefits enrollment code; type and date of incentive award; civil service or other legal authority; date probationary period begins; performance rating; due date for future action; position tenure; leave category; personnel authorized; projected personnel requirement; special experience identifies; additional duties; manpower track: facility; branch of service; date of rank; primary/Alternate specialty; control specialty; last OER/EER; total commissioned service date; total active service date; date of arrival; projected rotation date; security clearance; marital status; spouse's name; dependents; address (Number and street, city, state, Zip Code); phones (home and duty); handicap code; minority group designator; aggregate program element code; position indicator; academic degree requirements; directorate/department, division, branch, and section office titles; service authorization position number; physical profile; nature of action code No. 2; annuitant indicator; Vietnam veteran; entered present position; future action type; agency submitting element; submitting office code; merit pay designator; bargaining unit designator; old Social Security Number; course title host; tuition; Transportation Per Diem; hourly rate; training grade level; administrative cost; type of career training program.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

5 U.S.C. 301, 302, 4103; Pub. L. 89–554. September 6, 1966; and E.O. 9397.

PURPOSE(S):

For use by officials and employees of the Defense Nuclear Agency in the performance of their official duties related to the management of civilian and military employee programs and for preparation and publication of personnel rosters to facilitate communications/contact for official, or emergency purposes.

To compile and consolidate reports relating to manpower authorization/assigned strengths and to record personnel data and use that data to compile information as required by management officials within the agency.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

In addition to those disclosures generally permitted under 5 U.S.C. 552a(b) of the Privacy Act, these records or information contained therein may specifically be disclosed outside the DoD as a routine use pursuant to 5 U.S.C. 552a(b)(3) as follows:

Representatives of the Merit Systems Protection Board on matters relating to the inspection, survey, audit or evaluation of the civilian programs or such other matters under the jurisdiction of that organization.

The Comptroller General or any of his authorized representatives in the course of performance of duties of the General Accounting Office relating to civilian programs.

Duly appointed Hearing Examiners or Arbitrators for the purpose of conducting hearings in connection with an employee grievance.

The 'Blanket Routine Uses' published at beginning of DNA's compilation of systems of records notices apply to this system.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Automated records are stored on magnetic tapes, discs, computer printouts, and on punched cards. Manual records are stored in paper file folders and card file boxes.

RETRIEVABILITY:

Automated records are retrieved by employee name, Social Security Number or Position Service Number (PSN). Manual records are retrieved by employee's last name and PSN.

SAFEGUARDS:

The computer facility and data base are located in a restricted area accessible only to authorized personnel that are properly screened, cleared, and trained.

Terminal users are within a restricted area. Use of these terminals are by authorized personnel who have a need to acquire data from the database. Terminal users are cleared, provided proper training and are assigned a password/code to retrieve data. Manual records and computer printouts are available only to authorized personnel having a need to know. Buildings are protected by security guards and is protected by an intrusion alarm system.

RETENTION AND DISPOSAL:

Computer magnetic tapes are permanent. Manpower's manual records are maintained indefinitely and all personnel manual records are kept until the employee departs. Monthly reports are destroyed at the end of each fiscal year; annual reports are retained in 5–year blocks, transferred to the Washington National Records Center, and offered to National Archives and Records Administration 20 years after cutoff.

SYSTEM MANAGER(S) AND ADDRESS:

Assistant Director, Manpower Management and Personnel, Command Services Directorate, Headquarters, Defense Nuclear Agency, 6801 Telegraph Road, Alexandria, VA 22310–3398.

NOTIFICATION PROCEDURE:

Individuals seeking to determine whether information about themselves is contained in this system of records should address written inquiries to the Assistant Director, Manpower Management and Personnel, Command Services Directorate, Headquarters, Defense Nuclear Agency, 6801 Telegraph Road, Alexandria, VA 22310–3398.

The letter should contain the full name and signature of the requester and the approximate period of time, by date, during which the record was developed.

RECORD ACCESS PROCEDURES:

Individuals seeking access to information about themselves contained in this system of records should address written inquiries to the Assistant Director, Manpower Management and Personnel, Command Services Directorate, Headquarters, Defense Nuclear Agency, 6801 Telegraph Road, Alexandria, VA 22310–3398.

Written requests for information should contain the full name of individual. For personal visits, the individual should provide military or civilian identification card.

CONTESTING RECORD PROCEDURES:

The DNA rules for accessing records and for contesting contents and appealing initial agency determinations are published in DNA Instruction 5400.11A; 32 CFR part 318; or may be obtained from the system manager or the General Counsel, Headquarters, Defense Nuclear Agency, 6801 Telegraph Road, Alexandria, VA 22310–3398.

RECORD SOURCE CATEGORIES:

Information is extracted from military and civilian personnel records, Joint Manpower Program documents and voluntarily submitted by individual.

EXEMPTIONS CLAIMED FOR THE SYSTEM:

None.

HDNA 007

SYSTEM NAME:

Security Operations.

SYSTEM LOCATION:

Security Operations Division, Intelligence and Security, Command Services Directorate, Headquarters, Defense Nuclear Agency, 6801 Telegraph Road, Alexandria, VA 22310–3398.

System also exists at the following subordinate command: Security Division, Field Command, Defense Nuclear Agency, Kirtland Air Force Base, Albuquerque, NM 87115–5000.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

All military and civilian personnel assigned to, or employed by Headquarters, Defense Nuclear Agency (DNA); and the Field Command, Defense Nuclear Agency (FCDNA).

Other U.S. Government personnel, U.S. Government contractors, foreign government representatives, and visitors from foreign countries.

CATEGORIES OF RECORDS IN THE SYSTEM:

Name; Social Security Number; date and place of birth; height; weight; hair/eye color; citizenship; grade/rank; service; organization; security clearance; date of clearance; basis special accesses; courier authorization; continuous access roster expiration date; badge number; vehicle ID and sticker Number; special intelligence access; expiration date; agency; billet number; list of badges/passes issued; list of keys issued; conference title; conference duties; location; Department of Defense Form 398 'Statement of Personal History;' Reports of Investigation; security incident files; visit requests; conference rosters; clearance and special access rosters; picture identification; and correspondence concerning adjudication/passing of clearances.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

E.O. 10450, Security Requirements for Government Employment, 27 April 1953, as amended by E.O.s 10491, 10531, 10548, 10558, 11605, and 11785; E.O. 12065, 'National Security Information,' 28 June 1978; Section 21 of the Internal Security Act of 1950 (Pub. L. 831); Section 145 of the Atomic Energy Act of 1954, as amended by Pub. L. 83–703, 42 U.S.C. 2185; and E.O. 9397.

PURPOSE(S):

For use by officials and employees of the Defense Nuclear Agency and other DoD Components in the performance of their official duties related to determining the eligibility of individuals for access to classified information, access to buildings and facilities, or to conferences over which DNA has security responsibility.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

In addition to those disclosures generally permitted under 5 U.S.C. 552a(b) of the Privacy Act, these records or information contained therein may specifically be disclosed outside the DoD as a routine use pursuant to 5 U.S.C. 552a(b)(3) as follows:

Officials and employees of Government contractors and other Government agencies in the performance of their official duties related to the screening and selection of individuals for security clearances and/or special authorizations, access to facilities or attendance at conferences.

The 'Blanket Routine Uses' published at the beginning of DNA's compilation of systems of records notices apply to this system.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Automated records are stored on magnetic tapes, discs, computer printouts, and/or hard drives. Manual records are stored in paper file folders, card files and paper rosters.

RETRIEVABILITY:

Automated records are retrieved by individual's last name, conference title, and by type of badge issued. Manual records are retrieved by individuals last name, organization or subject file.

SAFEGUARDS:

The computer facility and terminals are located in restricted areas accessible only to authorized personnel. Manual records and computer printouts are available only to authorized persons

with an official need to know. Buildings are protected by security guards and an intrusion alarm system.

RETENTION AND DISPOSAL:

Computer records on individuals are erased upon termination of an individual's affiliation with DNA and FCDNA; personnel security files are destroyed within thirty days from the date of termination of an individual's employment, assignment or affiliation with DNA or FCDNA. Manual records or conference attendees, visitors, and visit certifications to other agencies are maintained for two years and destroyed. Security incident files are retained for two years unless they concern compromise of classified information, in which case they may be retained permanently.

SYSTEM MANAGER(S) AND ADDRESS:

For Headquarters DNA contact the Assistant Director, Intelligence and Security, Command Services Directorate, Headquarters, Defense Nuclear Agency, 6801 Telegraph Road, Alexandria, VA 22310–3398.

For Field Commands, DNA contact the Chief, Security Division, Field Command, Defense Nuclear Agency, Kirtland Air Force Base, NM 87115–5000.

NOTIFICATION PROCEDURE:

Individuals seeking to determine whether information about themselves is contained in this system of records should address written inquiries to the appropriate system manager.

RECORD ACCESS PROCEDURES:

Individuals seeking access to information about themselves contained in this system of records should address written inquiries to the appropriate system manager.

Written requests for information should contain the full name, home address, Social Security Number, date and place of birth. For personal visits, the individual must be able to provide identification showing full name, date and place of birth, and their Social Security Number.

CONTESTING RECORD PROCEDURES:

The DNA rules for accessing records and for contesting contents and appealing initial agency determinations are published in DNA Instruction 5400.11A; 32 CFR part 318; or may be obtained from the system manager or the General Counsel, Headquarters, Defense Nuclear Agency, 6801 Telegraph Road, Alexandria, VA 22310–3398.

RECORD SOURCE CATEGORIES:

Information is extracted from military and civilian personnel records, investigative files, and voluntarily submitted by individual.

EXEMPTIONS CLAIMED FOR THE SYSTEM:

Part of this system may be exempt under the provisions of 5 U.S.C. 552a(k)(5), as applicable.

An exemption rule for this system has been promulgated in accordance with the requirements of 5 U.S.C. 553(b)(1), (2), and (3), (c) and (e) and published in 32 CFR part 318. For additional information contact the system manager.

[FR Doc. 93–28695 Filed 11–22–93; 8:45 am]

BILLING CODE 5000–04–F

DEPARTMENT OF EDUCATION

Indian Education National Advisory Council; Meeting

AGENCY: National Advisory Council on Indian Education, Education.

ACTION: Notice of cancellation.

SUMMARY: This announcement is to notify to the public of the cancellation of a meeting of the National Advisory Council on Indian Education. Notice for this meeting was originally published in the Federal Register, Volume 58, page 58854 on Thursday, November 4, 1993. The National Advisory Council on Indian Education was originally scheduled to meet November 29–30, 1993, in Reno, Nevada. A notice will be published when the meeting is rescheduled.

Dated: November 18, 1993.

John W. Cheek,

Acting Director, National Advisory Council on Indian Education.

[FR Doc. 93–28791 Filed 11–22–93; 8:45 am]

BILLING CODE 4000–01–M

DEPARTMENT OF ENERGY

Office of Energy Efficiency and Renewable Energy

Notice of Meeting or Quality Metrics

SUMMARY: The U.S. Department of Energy's Office of Energy Efficiency and Renewable Energy (EE) is holding a meeting on the topic of "quality metrics." Representatives from various organizations have been invited to provide their views and thoughts concerning this issue.

DATES: The meeting will be held on December 8, 1993, at the Rosslyn West Park Hotel, 1900 Fort Myer Drive, Arlington, VA 22209, beginning at 9 a.m.

FOR FURTHER INFORMATION CONTACT: Murray Liebman, U.S. Department of Energy, Office of Energy Efficiency and Renewable Energy, EE–1, 1000 Independence Avenue, SW., Washington, DC 20585, (202) 586–9220.

SUPPLEMENTARY INFORMATION: The purpose of the meeting is to provide the Office of Energy Efficiency and Renewable Energy with the opportunity to hear views and opinions from various persons and stakeholder organizations on the development and application of performance measures for EE's programs. The quality metrics (QM) process will enable EE to measure and prioritize its program activities. Strategic plans and objectives will be translated into an analytical framework for measuring and evaluating EE program priorities. In addition, the process will ensure that EE's programs compliment the Department's mission, goals and objectives. Members of the public who do not receive a specific invitation to participate in the meeting will be given an opportunity to observe the meeting to the extent that there is room to accommodate them.

Issued in Washington, DC on November 18, 1993.

Frank Stewart,

Acting Assistant Secretary, Office of Energy Efficiency and Renewable Energy.

[FR Doc. 93–28788 Filed 11–22–93; 8:45 am]

BILLING CODE 6450–01–M

[Energy Research Financial Assistance Program Notice 94–06]

Office of Science Education and Technical Information; Experimental Program to Stimulate Competitive Research (EPSCoR)

AGENCY: U.S. Department of Energy (DOE).

ACTION: Notice inviting grant applications.

SUMMARY: The Office of Science Education and Technical Information (ET) of the U.S. Department of Energy (DOE), in keeping with its energy-related mission to assist in strengthening the Nation's human resource infrastructure through the support of science, engineering, and mathematics education at all levels of education, announces its interest in receiving applications from eligible States for the support of the DOE/EPSCoR Program. The purpose of the DOE/EPSCoR Program is to enhance the capabilities of designated States to conduct nationally competitive energy-

related research and to develop science and engineering manpower in energy-related areas to meet current and future needs in those areas. Subject to availability of funds, approximately $7 million will be available for awards under the DOE/EPSCoR Program in FY 1994 for collaborative research and manpower development in energy-related science and engineering disciplines.

DATES: Applications under this Notice should be received by 4:30 p.m. Eastern Standard Time, February 2, 1994.

ADDRESSES: Application materials are available from the Office of Science Education and Technical Information, ET–31, 1000 Independence Avenue SW., Washington, DC 20585. Telephone requests for application materials may be made by calling (202) 586–8949. The completed applications referencing Program Notice 94–06 must be submitted to: U.S. Department of Energy, Office of Energy Research, Acquisition and Assistance Management Division, ER–64, room F–220, Washington, DC 20585, ATTN: Program Notice 94–06. The following address must be used when submitting applications by U.S. Postal Service Express mail, any commercial mail delivery service, or when hand carried by the applicant: U.S. Department of Energy, Office of Energy Research, Acquisition and Assistance Management Division, ER–64, 19901 Germantown Road, Germantown, MD 20874. Telephone and telefax numbers must also be included in any application.

FOR FURTHER INFORMATION CONTACT: Ms. Donna J. Prokop, DOE/EPSCoR Program Manager, Office of Science Education and Technical Information, ET–31, U.S. Department of Energy, Washington, DC 20585. She may be reached by telephone on (202) 586–8949, fax: (202) 586–0019.

SUPPLEMENTARY INFORMATION: The House and Senate reports accompanying the FY 1994 Energy and Water Development Appropriation Bill (H.R. Rep. No. 135, 103rd Cong., 1st Sess., pg. 88. and S. Rep. No. 147, 103rd Cong., 1st Sess., pg. 97, respectively) recommended that $7 million be committed to continuing the DOE/EPSCoR program. In accordance with 10 CFR 600.7(b)(1), and to be consistent with the Congressionally recognized limitations, DOE has decided to continue to restrict eligibility to the following States and Territory: Alabama, Arkansas, Idaho, Kansas, Kentucky, Louisiana, Maine, Mississippi, Montana, Nebraska, Nevada, North Dakota, Oklahoma, South Carolina, South Dakota, Vermont, West Virginia, Wyoming, and the Commonwealth of Puerto Rico.

Awards issued under this Notice will implement plans formulated under the previously awarded DOE/EPSCoR planning grants. New awards will provide funding for state management and coordination, research collaboration, human resource development activities and traineeship activities. Approximately three to four new awards will be issued for a two-year period and up to a maximum of $1.25 million each for management and coordination, research collaboration, and human resource development activities. In addition, an optional award is available for a two-year period at a maximum of $250,000 for traineeships. The traineeship award must be tied to an identified DOE technical research area of interest. Any remaining balance of the estimated $7 million will be used to award funds to enable unsuccessful DOE/EPSCoR state committees to upgrade and refine state energy-related plans.

In addition, as a tangible measure of an applicant's commitment to the objectives of the DOE/EPSCoR program, cost-sharing on a one-to-one ratio is a requirement of this program, except for the DOE/EPSCoR traineeships. Therefore, each application submitted requesting support from DOE under this Notice must provide, from non-Federal funds, an amount equal to the amount awarded by the DOE; i.e., for every dollar provided by DOE, the recipient must provide a dollar from non-Federal sources for the project.

General information about development and submission of applications, eligibility, limitations, evaluation, and selection processes, and other policies and procedures are contained in the Application Guide for the Office of Energy Research Financial Assistance Program and in 10 CFR part 605. The Catalog of Federal Domestic Assistance number of this program is 81.049.

D.D. Mayhew,

Director, Office of Management, Office of Energy Research.

[FR Doc. 93–28706 Filed 11–22–93; 8:45 am]

BILLING CODE 6450–01–P

Notice of Public Meeting to Discuss Comments Received on the Preapproval Environmental Assessment for Interim Storage of Plutonium Components at Pantex Plant, Amarillo, TX

AGENCY: United States Department of Energy (DOE).

ACTION: Notice.

SUMMARY: The United States Department of Energy has scheduled a public meeting in Amarillo, Texas, on Monday, December 6, 1993, to discuss comments received from the State of Texas and stakeholders on the preapproval Environmental Assessment for Interim Storage of Plutonium Components at Pantex Plant, Amarillo, Texas. The Pantex Plant, located 17 miles northeast of Amarillo, Texas, is the United States' only nuclear weapons assembly and disassembly facility. It is being considered for expanded interim storage capacity for plutonium components removed from dismantled nuclear weapons.

DATES AND ADDRESSES: The public meeting will be held at the Amarillo Radisson Hotel, I–40 West and Lakeside Drive, Amarillo, Texas, 79104 from 9 a.m. to 9 p. m., Monday, December 6, 1993.

FOR FURTHER INFORMATION OR FOR A COPY OF THE ENVIRONMENTAL ASSESSMENT AND COMMENT RESPONSE DOCUMENT CONTACT: Thomas Walton, Public Affairs Officer, Amarillo Area Office, P.O. Box 30030, Amarillo, Texas 79120, (806) 477–3120.

SUPPLEMENTARY INFORMATION: Under the Department of Energy National Environmental Policy Act Implementing Procedures (10 CFR 1021.301), the Department is required to provide Environmental Assessments for review prior to approval to the host State(s) and Indian Tribes. A copy of an earlier version of this preapproval Environmental Assessment was provided to the State of Texas in December 1992. Subsequently, the State provided the preapproval Environmental Assessment to interested and affected members of the public. State and public comments on the preapproval Environmental Assessment were transmitted to the Department for consideration. At that time, the State also requested that the Department of Energy hold a public meeting to discuss the Department's resolution of comments.

On November 11, 1993, Secretary of Energy Hazel O'Leary provided copies of the preapproval Environmental Assessment, which has been revised on the basis of the comments received, and comment response document to State Officials and members of the public. In addition, a copy of that Environmental Assessment and the comment response document was mailed to each member of the public who provided comments on the original preapproval Environmental Assessment. Copies of the Environmental Assessment and

comment response document also were placed in the following local Department of Energy Reading Rooms:

U.S. Department of Energy Reading Room, Amarillo College, Lynn Library and Learning Center, P.O. Box 447, Amarillo, Texas 79178, Phone: (806) 371–5400.

U.S. Department of Energy Reading Room, Carson County Library, P.O. Box 339, Panhandle, Texas 79068, Phone: (806) 537–3742.

The purpose of the meeting is to provide the State and stakeholders an opportunity to discuss the revised Environmental Assessment and the Department's resolution of comments. All interested and affected individuals are invited to participate in the public meeting which will be held at the Amarillo Radisson Hotel, Amarillo, Texas, from 9 a.m. to 9 p.m. on Monday, December 6, 1993. During the morning and afternoon sessions (9 a.m. to 5 p.m.), the Department proposes to discuss specific technical issues raised in comments on the Environmental Assessment. During the evening session (6 p.m. to 9 p.m.), the morning and afternoon sessions will be summarized and the public will have further opportunity to ask questions and to discuss the Environmental Assessment. Department of Energy officials will be present and available to answer questions.

Issued in Washington, DC, on November 18, 1993.

Tara O'Toole,

Assistant Secretary, Environment, Safety and Health.

[FR Doc. 93–28751 Filed 11–22–93; 8:45 am]

BILLING CODE 6450–01–P

Waste Isolation Pilot Plant Land Management Plan

AGENCY: Department of Energy.

ACTION: Notice of availability.

SUMMARY: The Department of Energy (DOE) has prepared and issued a plan for the management of the withdrawn land at the Waste Isolation Pilot Plant (WIPP) until the decommissioning phase. In so doing, it is the intent of the land management plan to manage the withdrawal area under the traditional multiple-use concept and to minimize, to the extent possible, land use restrictions. In it not the intent of the DOE to manage the area as a WIPP exclusive-use area. The plan is available upon request.

ADDRESSES: The plan is available at the Public Reading Room (room 1E–190), U.S. Department of Energy, 1000 Independence Avenue, SW., Washington, DC 20585, Monday–Friday, excluding Federal holidays. Copies of the report have also been placed in the following WIPP reading rooms: WIPP Public Reading Room, National Atomic Museum, U.S. Department of Energy, Albuquerque Operations Office, P.O. Box 5400, Albuquerque, New Mexico 87115; Thomas Brannigan Memorial Library, 200 E. Picacho, Las Cruces, New Mexico 88005; New Mexico State Library, 325 Don Gaspar, Santa Fe, New Mexico 87503; Pannell Library, New Mexico Junior College, 5317 Lovington Highway, Hobbs, New Mexico 88240; Carlsbad Public Library, 101 S. Halagueno, Carlsbad, New Mexico 88220; Zimmerman Library, Government Publications Department, University of New Mexico, Albuquerque, New Mexico 87138; and Martin Speare Memorial Library, New Mexico Tech, Campus Station, Socorro, New Mexico 87801.

FOR FURTHER INFORMATION CONTACT: Ms. Patty Baratti-Sallani, Waste Isolation Pilot Plant Project Site Office, U.S. Department of Energy, P.O. Box 3090, Carlsbad, New Mexico 88220, at (505) 234–7337.

SUPPLEMENTARY INFORMATION: WIPP is a research and development facility located in Southeastern New Mexico with the mission of demonstrating the safe shipment and disposal of radioactive wastes resulting from defense activities and programs of the United States. This plan, a requirement of section 4(b)(1) of the WIPP Land Withdrawal Act (Pub. L. 102–579), has been prepared in consultation with the Bureau of Land Management (BLM) and the State of New Mexico. In addition, two public information meetings were held in July 1993 to brief the public and to answer any questions. As a complement to this land management plan, a Memorandum of Understanding (MOU) shall be executed between the DOE and the BLM, as required by Section 4(d) of the Act. This MOU will also be made available in the aforementioned reading rooms. This MOU, which will remain in effect until the end of the decommissioning phase, will serve to implement the management plan.

Issued in Washington, DC, on November 2, 1993.

Thomas P. Grumbly,

Assistant Secretary for Environmental Restoration and Waste Management.

[FR Doc. 93–28705 Filed 11–22–93; 8:45 am]

BILLING CODE 6450–01–M

ENVIRONMENTAL PROTECTION AGENCY

Office of Research and Development

[FRL–4805–3]

Ambient Air Monitoring Reference and Equivalent Methods; Equivalent Method Designation

Notice is hereby given that EPA, in accordance with 40 CFR part 53, has designated another equivalent method for the determination of lead in suspended particulate matter collected from ambient air. The new designated method is identified as follows:

EQL–1193–094, "Determination of Lead Concentration in Ambient Particulate Matter by Inductively Coupled Argon Plasma Optical Emission Spectrometry (State of Illinois)."

The applicant's request for an equivalent method determination for the above method was received on April 6, 1993. Additional requested information pertinent to the original submittal was received on September 9, 1993.

This method has been tested by the applicant, the Illinois Environmental Protection Agency, in accordance with the test procedures prescribed in 40 CFR part 53. After reviewing the results of these tests and other information submitted by the applicant, EPA has determined, in accordance with part 53, that this method should be designated as an equivalent method. The information submitted by the applicant will be kept on file at EPA's Atmospheric Research and Exposure Assessment Laboratory, Research Triangle Park, North Carolina, and will be available for inspection to the extent consistent with 40 CFR part 2 (EPA's regulations implementing the Freedom of Information Act).

This method uses the sampling procedure specified in the reference method for the determination of lead in suspended particulate matter collected from ambient air (43 FR 46258). Lead in the particulate matter is solubilized by extraction with nitric acid facilitated by heat (hot plate). The lead content of the sample is analyzed by a Jarrel Ash 61E inductively coupled argon plasma optical emission spectrometer using the 220.35 nm lead emission line and instrument conditions optimized by the user laboratory. Technical questions concerning the method should be directed to the State of Illinois, Environmental Protection Agency, Champaign Inorganics Laboratory, 2120 South First Street, Champaign, Illinois 61820.

As a designated equivalent method, this method is acceptable for use by

states and other control agencies under requirements of 40 CFR part 58, Ambient Air Quality Surveillance. For such purposes the method must be used in strict accordance with the procedures and specifications provided in the method description. States or other agencies using inductively coupled argon plasma optical emission spectrometric methods that employ procedures and specifications significantly different from those in this method must seek approval for their particular method under the provisions of § 2.8 of appendix C to 40 CFR part 58 (Modification of Methods by Users) or may seek designation of such methods as equivalent methods under the provisions of 40 CFR part 53.

Additional information concerning this action may be obtained from Frank F. McElroy, Methods Research and Development Division (MD–77), Atmospheric Research and Exposure Assessment Laboratory, U.S. Environmental Protection Agency, Research Triangle Park, North Carolina 27711, telephone (919) 541–2622.

Carl Gerber,

Acting Assistant Administrator for Research and Development.

[FR Doc. 93–28736 Filed 11–22–93; 8:45 am]

BILLING CODE 6560–50–M

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. ER94–150–000, et al.]

PacifiCorp, et al., Electric Rate, Small Power Production, and Interlocking Directorate Filings

November 17, 1993.

Take notice that the following filings have been made with the Commission:

1. PacifiCorp

[Docket No. ER94–150–000]

Take notice that on November 15, 1993, PacifiCorp tendered for filing, in accordance with 18 CFR 35 of the Commission's Rules and Regulations, a Emergency Interconnection Agreement between Fall River Rural Electric Cooperative, Inc. and PacifiCorp dated October 21, 1993.

Copies of this filing have been supplied to the Idaho Public Utilities Commission and the Public Utility Commission of Oregon.

Comment date: December 2, 1993, in accordance with Standard Paragraph E at the end of this notice.

2. Boston Edison Co.

[Docket No. ER94–149–000]

Take notice that on November 15, 1993, Boston Edison Company (Edison) tendered for filing for informational purposes only a specification for interconnection services to the Reading Municipal Light Department (RMLD) for the period from November 1, 1993 through October 31, 1997.

Edison states that it has served the filing on RMLD and the Massachusetts Department of Public Utilities.

Comment date: December 2, 1993, in accordance with Standard Paragraph E at the end of this notice.

3. Maine Electric Power Company, Inc.

[Docket No. ES94–5–001]

Take notice that on November 12, 1993, Maine Electric Power Company, Inc. (Maine Electric) filed an amendment to its application in Docket No. ES94–5–000 under section 204 of the Federal Power Act seeking authorization to issue up to $9.5 million of unsecured notes or other unsecured short-term obligations to be issued on or before December 31, 1995, with a maturity of one year or less after date of issuance, in lieu of the $15 million originally proposed.

Comment date: December 1, 1993, in accordance with Standard Paragraph E at the end of this notice.

4. Atlantic City Electric Co.

[Docket No. ER94–151–000]

Take notice that on November 15, 1993, Atlantic City Electric Company (AE) tendered for filing as an initial Rate Schedule an Agreement for Installed Capacity Credit Transactions between GPU Service Corporation (GPU), acting as agent for Jersey Central Power and Light Company, Metropolitan Edison Company and Pennsylvania Electric Company and AE dated November 5, 1993. This contract sets forth the terms under which AE will sell PJM installed capacity credits to GPU. In order to maximize the economic advantages to both AE and GPU, AE requests that the Commission waive its customary notice period and permit this Agreement to become effective on November 15, 1993.

AE states that a copy of this filing have been served by mail on GPU, the New Jersey Board of Regulatory Commissioners, and the Pennsylvania Public Utility Commission.

Comment date: December 2, 1993, in accordance with Standard Paragraph E at the end of this notice.

5. Florida Power & Light Co.

[Docket No. ER94–137–000]

Take notice that on November 9, 1993, Florida Power & Light Company (FPL) tendered for filing Amendment Number Sixteen To Revised Agreement To Provide Specified Transmission Service Between Florida Power & Light Company And Tampa Electric Company (Amendment No. 16). FPL requests that Amendment No. 16 be made effective November 10, 1993.

Comment date: December 2, 1993, in accordance with Standard Paragraph E at the end of this notice.

6. Northeast Utilities Service Co.

[Docket No. ER94–136–000]

Take notice that on November 9, 1993, Northeast Utilities Service Company (NUSCO), on behalf of The Connecticut Light and Power Company, Western Massachusetts Electric Company (WMECO), Holyoke Water Power Company, Holyoke Power and Electric Company and Public Service Company of New Hampshire, tendered for filing a Second Amendment to Transmission Service Agreement and a Second Amendment to Distribution and Transformation Agreement for service to New England Power Company (NEP). These rate schedule changes implement the terms of a Settlement Agreement accepted by the Commission to provide for delivery of power from NEP to the Massachusetts Electric Company's (MASS Electric) load at Brodie Mountain Road in lieu of firm requirements service from WMECO to this Mass Electric load.

NUSCO requests that these two Second Amendments be permitted to become effective November 1, 1993, and be permitted to supersede WMECO's requirements service to the Mass Electric load at Brodie Mountain Road.

Comment date: December 2, 1993, in accordance with Standard Paragraph E at the end of this notice.

7. New England Power Co.

[Docket No. ER94–148–000]

Take notice that New England Power Company (NEP), on November 15, 1993, tendered for filing seven (7) Unit Power Contracts between NEP and (1) Boston Edison Company; (2) Town of Braintree Electric Light Department; (3) Fitchburg Gas and Electric Light Department; Massachusetts Municipal Wholesale Electric Company; Northeast Utilities Service Company; Public Service Company of New Hampshire; and Taunton Municipal Lighting Plant for the sale of capacity from several of NEP's generation units.

Pursuant to the Commission's Final Order in Docket No. PL93–2–000, dated July 31, 1993, NEP requests waiver of the Commission's notice requirements so that the Contracts can be made effective and simultaneously terminated.

Comment date: December 2, 1993, in accordance with Standard Paragraph E at the end of this notice.

8. North American Energy Conservation, Inc.

[Docket No. ER94–152–000 and EL94–9–000]

Take notice that North American Energy Conservation, Inc., (NAEC) on November 12, 1993, tendered for filing pursuant to Rule 207 of the Commission's Rules of Practice and Procedure, 18 CFR 285.207 (1992), a petition for waivers and blanket approvals under various regulations of the Commission, and also filed its Rate Schedule No. 1, to be effective as of January 1, 1994.

NAEC intends to engage in electric power and energy transactions as a marketer and a broker. In transactions where NAEC sells power as a marketer, it proposes to make such sales on rates, terms, and conditions to be mutually agreed upon with the purchasing party. Rate Schedule No. 1 provides for the sale of power under such agreements. All sales will be at arms-length, and no sales will be made to affiliated entities. In transactions where NAEC does not take title to the electric power and/or energy, NAEC will be limited to the role of a broker and charge a fee for its services. NAEC is not in the business of producing or transmitting electric power. NAEC does not currently have or contemplate acquiring title to any electric power transmission or generation facilities.

Comment date: December 6, 1993, in accordance with Standard Paragraph E at the end of this notice.

9. Genesee Power Station Limited Partnership

[Docket Nos. ES94–7–000 and ES94–7–001]

Take notice that on November 12, 1993, Genesee Power Station Limited Partnership (Genesee) filed an application and on November 16, 1993, filed an amendment under section 204 of the Federal Power Act seeking authorization to enter into a long-term loan agreement for up to $65 million of tax-exempt bonds, to enter into a long-term bank term loan for up to $26 million of promissory notes and for blanket approval of all other future issuances of securities and assumptions of liabilities. Also, Genesee requests exemption from the Commission's competitive bidding and negotiated placement regulations.

Comment date: December 6, 1993, in accordance with Standard Paragraph E at the end of this notice.

10. Edison Sault Electric Company

[Docket No. ES94–8–000]

Take notice that on November 15, 1993, Edison Sault Electric Company filed an application under section 204 of the Federal Power Act seeking authorization to issue not more than $10 million of unsecured short-term notes on or before December 31, 1995, with a maturity date no later than December 31, 1996.

Comment date: December 14, 1993, in accordance with Standard Paragraph E at the end of this notice.

11. New England Power Pool

[Docket No. ER93–985–000]

Take notice that on November 15, 1993, twenty-nine participants in the New England Power Pool (the Filing Participants) filed additional information concerning the Thirtieth Amendment to the New England Power Pool (NEPOOL) Agreement (the Amendment), which had been filed with the Commission on September 29, 1993. The additional information submitted by the Filing Participants constitutes an amendment to the original filing and has been submitted in response to the Commission's October 26, 1993, letter in the captioned docket that requested additional information concerning the Amendment.

The Filing Participants have provided additional details concerning each revision to the NEPOOL Agreement made by the Amendment. Specifically, the Filing Participants state that they have provided a detailed comparison of the present and revised sections of the NEPOOL Agreement, and a detailed explanation of, and justification for, each revision and the impact of each revision on NEPOOL participants. The Filing Participants also state that they have provided additional information which demonstrates that the revisions to the NEPOOL Agreement contained in the Amendment are reasonable and are consistent with the objectives specified in the NEPOOL Agreement and all applicable pool procedures.

The Filing Participants have renewed their request that the Commission waive the customary notice period and permit the Amendment to become effective as of September 30, 1993.

Comment date: December 2, 1993, in accordance with Standard Paragraph E at the end of this notice.

12. Florida Power Corp.

[Docket No. ER94–144–000]

Take notice that on November 10, 1993, Florida Power Corporation filed (1) a supplement to an Exhibit C to the Service Agreement between itself and Tampa Electric Company and (2) an Exhibit A to that supplement. The Supplement and Exhibit A describe service which Tampa Electric has agreed to provide to the City of St. Cloud beginning January 1, 1994, and extending through December 31, 2012 and which will be wheeled by Florida Power under the T–1 tariff and Florida Power's Service Agreement with Tampa Electric. Florida Power requests waiver of the notice requirement to permit the Supplement and Exhibit A to become effective on January 1, 1994, when Tampa Electric's service to St. Cloud will commence.

Comment date: December 2, 1993, in accordance with Standard Paragraph E at the end of this notice.

13. CRSS Power Marketing, Inc.

[Docket No. ER94–142–000]

Take notice that CRSS Power Marketing, Inc. (the Petitioner) on November 9, 1993, tendered for filing pursuant to Rule 207 of the Commission's Rules of Practice and Procedure, 18 CFR 385.207 (1993), a petition for waivers and blanket approvals under various regulations of the Commission and an order accepting its Rate Schedule No. 1.

The Petitioner intends to engage in wholesale electric power transactions as a marketer. The Petitioner will purchase power, including capacity and related services from electric utilities, qualifying facilities and independent power producers, and resell such power to other purchasers. The Petitioner proposes to charge rates mutually agreed upon by the parties. No sales will be made to affiliated entities. The Petitioner is not in the business of producing or transmitting electric power. The Petitioner does not currently have or contemplate acquiring title to any electric power transmission or generation facilities.

Rate Schedule No. 1 provides for the sale of energy and capacity at agreed prices. Rate Schedule No. 1 also provides that no sales may be made to affiliates.

Comment date: December 2, 1993, in accordance with Standard Paragraph E at the end of this notice.

14. WestPlains Energy, a Division of UtiliCorp United, Inc.

[Docket No. ER94–140–000]

Take notice that on November 9, 1993, WestPlains Energy, a division of UtiliCorp United, Inc. (WestPlains) tendered for filing an Agreement with Kansas Electric Power Cooperative, Inc. (KEPCo) to extend service under Service Schedule 92–I–2 for the period from June 1 to September 30, 1993. Pursuant to the amnesty established by the Commission in Docket No. PL93–2–002, Prior Notice and Filing Requirements Under Part II of the Federal Power Act, 64 FERC ¶ 61,138 (1993), an effective date of June 1, 1993, is requested.

A copy of the filing was served upon KEPCo and the Kansas Corporation Commission.

Comment date: December 2, 1993, in accordance with Standard Paragraph E at the end of this notice.

Standard Paragraphs

E. Any person desiring to be heard or to protest said filing should file a motion to intervene or protest with the Federal Energy Regulatory Commission, 825 North Capitol Street, NE., Washington, DC 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 18 CFR 385.214). All such motions or protests should be filed on or before the comment date. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a motion to intervene. Copies of this filing are on file with the Commission and are available for public inspection.

Lois D. Cashell,

Secretary.

[FR Doc. 93–28758 Filed 11–22–93; 8:45 am]

BILLING CODE 6717–01–P

[Docket Nos. CP93–618–000 and CP93–685–000]

Pacific Gas Transmission Co. and Tuscarora Gas Transmission Co.; PGT/Tuscarora Pipeline Project; Intent/Preparation To Prepare a Draft Environmental Impact Report/Statement for the Proposed PGT Expansion II and Tuscarora Projects and Request for Comments on Environmental Issues

November 17, 1993

The staff of the Federal Energy Regulatory Commission (FERC or Commission) will prepare a joint environmental impact report/statement (EIR/EIS) with the California State Lands Commission (SLC) that will discuss environmental impacts of the construction and operation of facilities proposed in the PGT Expansion II and Tuscarora Projects (known hereafter as the PGT/Tuscarora Pipeline Project).[1] This EIR/EIS will be used by the Commission in its decision-making process (whether or not to approve the individual projects).

The California SLC will be cooperating with us because of the significant amount of California state lands affected by the proposals. The FERC will be the lead Federal agency and, with the California SLC as the lead State agency for California, will produce this joint EIR/EIS satisfying the requirements of the California Environmental Quality Act (CEQA) and the National Environmental Policy Act (NEPA), respectively.

The Bureau of Land Management (BLM) will be cooperating with us in the preparation of the EIR/EIS because of the amount of BLM-managed land that would be affected by the proposals and because this proposed action may include one or more planning amendments by the BLM. The other Federal agencies being asked to cooperate (see Appendix 1) may choose to participate once they have evaluated each proposal relative to their agencies' responsibilities.

Summary of the Proposed Facilities

The PGT/Tuscarora Pipeline Project is a natural gas pipeline proposal involving construction of natural gas transmission facilities in Oregon, Washington, Idaho, California, and Nevada. Appendices 2 and 3 list the proposed PGT/Tuscarora pipeline facilities. The general locations of both the PGT/Tuscarora facilities are shown on appendices 4 and 5.[2]

In Docket No. CP93–618–000, PGT proposes to construct and operate 102 miles of new 12-inch-diameter pipeline lateral in two segments in Oregon. The Coyote Springs Extension Lateral would consist of 17.71 miles of new pipeline connecting PGT's mainline system between Lexington and Pine City, and extending to Portland General Electric's (PGE) proposed cogeneration facility near Boardman. All facilities would be located in Morrow County, Oregon. Two 12-inch mainline valve sites and one new meter station are also proposed. The purpose of the Coyote Springs Extension Lateral is to enable PGT to transport 41 decatherms (Dth) per day of natural gas for PGE.

The Medford Extension Lateral would consist of 84.17 miles of new pipeline extending between PGT's mainline system at Compressor Station 14 near Bonanza, Oregon and terminating near Medford, Oregon. Seven 12-inch mainline valve sites, two meter stations, and communication equipment are also proposed. All facilities would be located in Klamath and Jackson Counties, Oregon. The purpose of the Medford Extension Lateral is to transport natural gas to WP Natural Gas Company's distribution system in southern Oregon.

To transport the volume of gas required by PGT and Tuscarora, PGT's pipeline system upstream of Malin, Oregon, must undergo minor modifications and improvements. PGT plans to add approximately 14,000 to 16,000 horsepower to existing compressor stations at Sandpoint, Idaho, and Rosalia, Washington; and to add three meter runs inside its existing Malin Meter Station in southern Oregon.

In Docket No. CP93–685–000, Tuscarora proposes to construct and operate 229 miles of new 20-inch-diameter pipeline. The pipeline would extend from Malin, Klamath County, Oregon, southward through the Modoc National Forest in Modoc County, California, where it would head southeast into Lassen County and terminate in Storey County, Nevada. No compressor facilities are proposed. The purpose of the Tuscarora Project is to transport approximately 113,050 Dth per day of natural gas to its prospective shippers.

Three laterals in California are also proposed. The Alturas Lateral would consist of 5.3 miles of 4-inch-diameter pipeline extending between the Tuscarora Mainline and Alturas, in Modoc County, California. The Susanville Lateral would consist of 10.7 miles of 6-inch-diameter pipeline extending between the Tuscarora Mainline and Leavitt, Lassen County, California. The Herlong Lateral would consist of 5.5 miles of 4-inch-diameter pipeline extending between the Tuscarora Mainline and the Sierra Army Depot, in Lassen County, California.

Five meter stations are proposed: Alturas, Susanville, and Herlong (Sierra Army Depot) in California; and Spanish Springs and Tracy in Nevada.

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[1] Pacific Gas Transmission Company's and Tuscarora Gas Transmission Company's applications were filed with the Commission pursuant to section 7 of the Natural Gas Act and part 157 of the Commission's regulations.

[2] Tables and figures referenced in this notice are not printed in the **Federal Register**, but have been sent to all those receiving this notice. Copies are also available from the Commission's Public Reference Branch, room 3104, 941 North Capitol Street, NE., Washington, DC 20426 or call (202) 208–1371.

Land Requirements/Construction Procedures

PGT's portion of the proposed pipeline would be built within a 65-foot-wide construction right-if-way; Tuscarora proposes a 100-foot-wide width.

Construction of the pipelines would normally follow standard pipeline construction methods: Right-of-way clearing and grading; trenching; pipe stringing, bending, welding, joint coating, and lowering in; backfilling of the trench; and cleanup and restoration. The applicants propose to implement erosion control and revegetation measures and to use special construction techniques for wetland and water crossings and for construction in residential areas. These construction procedures and mitigation plans will be discussed further in the draft EIR/EIS.

Pipeline segments would be hydrostatically tested according to U.S. Department of Transportation minimum safety standards and specifications (49 CFR part 192) before being placed in service. No chemicals would be used during testing, and the applicants would be required to obtain appropriate Federal and state discharge permits prior to testing.

The EIR/EIS Process

The NEPA requires the Commission to take into account the environmental impacts that could result from a major Federal action whenever it considers the issuance of a Certificate of Public Convenience and Necessity. The California SLC, as a cooperating state agency, is required to consider the same potential impacts within the state of California under the CEQA. The EIR/EIS we are preparing will give both the Commission and the SLC the information we need to do that. NEPA (and CEQA) also requires us to discover and address concerns the public may have about proposals. We call this "scoping". The main goal of the scoping process is to focus the analysis in the EIR/EIS on the important environmental issues, and to separate those issues that are insignificant and do not require detailed study.

The EIR/EIS will discuss impacts that could occur as a result of the construction and operation of the proposed projects under these subject headings (but are not limited to):

Geology and Soils
- —Erosion control
- —Geological hazards
- —Right-of-way restoration and maintenance
- —Effect on cropland

Water Resources
- —Effect on potable water supplies
- —Effect on surface water quality
- —Impact on wetland hydrology
- —Impact of stream and river crossings on water flow

Biological Resources
- —Impact on wetlands
- —Impact on forestlands and habitat alteration
- —Short-and long-term effects of right-of-way clearing and maintenance
- —Impact on threatened and endangered species
- —Indirect effect on Modoc National Wildlife Refuge

Cultural Resources
- —Effect on properties listed on or eligible for the National Register of Historic Places
- —Native American and tribal concerns
- —National Historical Trail Study Area concerns
- —Effect on known archaeological sites

Land Use
- —Impact on residences
- —Impact on public lands
- —Impact on agricultural land
- —Impact on commercial and industrial areas
- —Impact on aesthetic resources
- —Impact on recreational areas
- —Impact on present or planned use of an area

Socioeconomics
- —Effects on population growth and displacement
- —Effects on employment

Air quality
- —Effect of compressor station operation on air quality

Noise
- —Effect on compressor station operation on nearby noise-sensitive receptors

Reliability and Safety
- —Risk assessment of hazards associated with natural gas pipelines

Alternatives
- —Route variations to avoid sensitive areas

Cumulative Impacts
- —Identification of related projects
- —Analysis of cumulative impacts and mitigation measures

We will also evaluate possible alternatives to the projects, or portions of the projects, and make recommendations on how to lessen or avoid impacts on the various resource areas.

Our independent analysis of the issues will result in the publication of a Draft EIR/EIS which will be mailed to Federal, state, and local agencies, public interest groups, interested individuals, affected landowners, newspapers, libraries, and the Commissions's official service list for these proceedings. A 45-day comment period will be allocated for the review of the Draft EIR/EIS. We will consider all comments on the Draft EIR/EIS and revise the document, as necessary, before issuing a Final EIR/EIS. The Final EIR/EIS will include our response to each comment received.

Public Participation and Scoping Meetings

You can make a difference by sending a letter with your specific comments or concerns about the projects. You should focus on the potential environmental effects of the proposals, alternatives to the proposals, (including alternative routes), and measures to avoid or lessen environmental impact. The more specific your comments, the more useful they will be. Please follow the instructions below to ensure that your comments are received and properly recorded:

- Address the letter to: Ms. Lois Cashell, Secretary, Federal Energy Regulatory Commission, 825 North Capitol Street, NE., Washington, DC 20426;
- Reference Docket No. CP93–618–000 or CP93–685–000;
- Send a copy of the letter to the following individuals:

Alisa M. Lykens, EIS Project Manager, Federal Energy Regulatory Commission, Office of Pipeline and Producer Regulation, room 7312, 825 North Capitol Street, NE., Washington, DC 20426

Kirk Walker, EIR Project Manager, State Lands Commission, 1807 13th Street, Sacramento, CA 95814;

- Mail comments before December 20, 1993.

In addition to asking for written comments, we invited you to attend any of the scoping meetings listed on the following page. The meetings will be designed to provide you with more detailed information and another opportunity to offer your comments on the proposed projects. Those wanting to speak at the meetings can call the EIS Project Manager to pre-register their names on the speakers' list. Those people on the speakers' list prior to the date of the meeting will be allowed to speak first. A second speakers' list will be available at the meeting. Priority will be given to people representing groups. A transcript of each meeting will be made so that your comments will be accurately recorded.

Schedule for EIR/EIS Scoping Meetings PGT/Tuscarora Pipeline Project

Sparks, Nevada, December 6, 1993; 7 p.m., Best Western, McCarran House Inn, 55 East Nugget Avenue, Sparks, Nevada 89431, (702) 358–6900

Susanville, California, December 7, 1993; 7 p.m., The Monticola Club, 140 South Lassen Street, Susanville, California 96130, (916) 257–2345

Medford, Oregon, December 8, 1993; 7 p.m., Red Lion Motor (Crater Room), Medford, Oregon 97501, (503) 779–5811

Becoming an Intervenor

In addition to involvement in the EIR/EIS scoping process, you may want to become an official party to the FERC proceedings or an "intervenor". Among other things, intervenors have the right to receive copies of case-related Commission documents and filings by other intervenors. Likewise, each intervenor must provide copies of its filings to all other parties. If you want to become an intervenor, you must file a Motion to Intervene according to Rule 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.214) which is attached as appendix 6.

Environmental Mailing List

If you don't want to send comments at this time but still want to keep informed and receive copies of the Draft and Final EIR/EIS, please return the Information Request (appendix 7). If you don't return the information Request, you will be taken off the mailing list. Additional information about the proposed projects is available from Ms. Alisa Lykens, EIS Project Manager, (202) 208–0766.

Information concerning the involvement of the California SLC in the EIR/EIS may be obtained from: Kirk Walker, 1807 13th Street, Sacramento, California 95814, Telephone (916) 322–0530

As of this notice the FERC is aware that the Bureau of Land Management (BLM) will be a cooperating agency. The BLM contacts for the environmental analysis are:

Tuscarora Project

Pete Humm, BLM—Susanville District, 705 Hall Street, Susanville, California 96130, Telephone (916) 257–5381

PGT Project

Tom Cottingham, BLM Klamath Falls Resource Area 2795 Anderson Ave.—Bldg. 25 Klamath Falls, OR 97603 Telephone (503) 885–4210

Lois D. Cashell,

Secretary.

[FR Doc. 93–28655 Filed 11–22–93; 8:45 am]

BILLING CODE 6717–01–M

[Docket No. JD94–01058T Texas–154]

State of Texas; NGPA Notice of Determination by Jurisdictional Agency Designating Tight Formation

November 17, 1993.

Take notice that on November 5, 1993, the Railroad Commission of Texas (Texas) submitted the above-referenced notice of determination pursuant to § 271.703(c)(3) of the Commission's regulations, that the L–12, L–13, L–14, L–24, L–25, and L–26 zones of the Wilcox Sand Formation, underlying a portion of Zapata County, Texas, qualifies as a tight formation under section 107(b) of the Natural Gas Policy Act of 1978. The designated area lies in Railroad Commission District No. 4. The area occupies approximately 1,286 acres in a portion of Porcion 14, Bernard Gutierrez Survey, A–34 and Porcion 15, Jose Clement Gutierrez Survey, A–35.

The notice of determination also contains Texas' findings that the referenced portions of the Wilcox Formation meet the requirements of the Commission's regulations set forth in 18 CFR part 271.

The application for determination is available for inspection, except for material which is confidential under 18 CFR 275.206, at the Federal Energy Regulatory Commission, 825 North Capitol Street, N.E., Washington, DC 20426. Persons objecting to the determination may file a protest, in accordance with 18 CFR 275.203 and 275.204, within 20 days after the date this notice is issued by the Commission.

Lois D. Cashell,

Secretary.

[FR Doc. 93–28656 Filed 11–22–93; 8:45 am]

BILLING CODE 6717–01–M

[Project No. 10998–001 Oregon]

Ochoco Irrigation District; Surrender of Preliminary Permit

November 17, 1993.

Take notice that Ochoco Irrigation District, Permittee for the Prineville Project No. 10998, has requested that its preliminary permit be terminated. The preliminary permit for Project No. 10998 was issued March 18, 1991, and would have expired February 28, 1994. The project would have been located on lands administered by the Bureau of Reclamation, on the Crooked River in Crook County, Oregon.

The Permittee filed the request on November 5, 1993, and the preliminary permit for Project No. 10998 shall remain in effect through the thirtieth day after issuance of this notice unless that day is a Saturday, Sunday or holiday as described in 18 CFR 385.2007, in which case the permit shall remain in effect through the first business day following that day. New applications involving this project site, to the extent provided for under 18 CFR part 4, may be filed on the next business day.

Lois D. Cashell,

Secretary.

[FR Doc. 93–28657 Filed 11–22–93; 8:45 am]

BILLING CODE 6717–01–M

[Docket Nos. RP93–14–000, et al., RP93–126–000, et al., RP87–14–000, et al., RP86–41–000, et al.]

Algonquin Gas Transmission Co.; Informal Settlement Conference

Take notice that an informal settlement conference will be convened in these proceedings on December 6, 1993 at 10 a.m. at the offices of the Federal Energy Regulatory Commission, 810 First Street, NE., Washington, DC 20426, for the purpose of exploring the possible settlement of the issues in this proceeding.

Any party, as defined by 18 CFR 385.102(c), or any participant as defined by 18 CFR 385.102(b), is invited to attend. Persons wishing to become a party must move to intervene and receive intervenor status pursuant to the Commission's regulations (18 CFR 385.214).

For additional information, contact Marc G. Denkinger (202) 208–2215 or David R. Cain (202) 208–0917.

Lois D. Cashell,

Secretary.

[FR Doc. 93–28659 Filed 11–22–93; 8:45 am]

BILLING CODE 6717–01–M

[Docket No. RP94–43–001]

ANR Pipeline Co.; Proposed Changes in FERC Gas Tariff

November 17, 1993.

Take notice that on November 12, 1993, ANR Pipeline Company (ANR) tendered for filing, proposed changes in its FERC Gas Tariff, Second Revised Volume No. 1, to become effective

December 1, 1993. On November 1, 1993, ANR Pipeline Company (ANR) filed with the Commission in the referenced docket an application for a general rate increase pursuant to section 4 of the Natural Gas Act (NGA). In that filing, ANR submitted three alternative cases. ANR supplements its November 1, 1993, rate filing for the purpose of offering additional options to its shippers under the third case as more fully set forth in the application on file with the Commission.

Any person desiring to protest said filing should file a protest with the Federal Energy Regulatory Commission, 825 North Capitol Street, NE., Washington, DC 20426, in accordance with Rule 211 of the Commission's Rules of Practice and Procedure (18 CFR 385.211). All such protests should be filed on or before November 24, 1993. Protests will be considered by the Commission in determining the appropriate action to be taken but will not serve to make protestants parties to the proceedings. Copies of this filing are on file with the Commission and are available for public inspection.

Lois D. Cashell,

Secretary.

[FR Doc. 93–28660 Filed 11–22–93; 8:45 am]

BILLING CODE 6717–01–M

[Docket No. RS92–64–001]

High Island Offshore System; Compliance Filing

November 17, 1993.

Take notice that on November 10, 1993, High Island Offshore System ("HIOS") filed tariff sheets to comply with and implement the line pack gas settlement that was approved in the captioned proceeding by the Federal Energy Regulatory Commission by Letter Order dated October 12, 1993. HIOS requests, consistent with the settlement, that tariff sheets which includes a $.0017 per Mcf line pack surcharge, be accepted effective on November 1, 1993.

Any person desiring to protest said filing should file a motion to intervene or protest with the Federal Energy Regulatory Commission, 825 North Capitol Street, NE., Washington, DC 20426, in accordance with Rule 211 and Rule 214 of the Commission's Rules of Practice and Procedure 18 CFR 385.211, 385.214. Any such protests and motions to intervene should be filed on or before December 1, 1993. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party mist file a motion to intervene. Copies of this filing are on file with the Commission and are available for public inspection in the Public Reference Room.

Lois D. Cashell,

Secretary.

[FR Doc. 93–28662 Filed 11–22–93; 8:45 am]

BILLING CODE 6717–01–M

[Docket No. RP93–206–001]

Proposed Changes in FERC Gas Tariff

November 17, 1993

Take notice that on November 12, 1993, Northern Natural Gas Company (Northern) tendered for filing to become part of its FERC Gas Tariff, Fifth Revised Volume No. 1, the following tariff sheets, proposed to be effective November 1, 1993:

First Revised Sheet No. 263
Orignial Sheet No. 263A

Northern states that such tariff sheets are being submitted in compliance with the Commission's Order issued October 28, 1993, in Docket No. RP93–206–000 to revise the tariff to incorporate the operational conditions as set forth in the "Resolution of Supply Commitment at Carlton" filed on September 30, 1993, as amended on October 20, 1993.

Northern further states that copies of the filing have been mailed to each of its customers and interested state commissions.

Any person desiring to protest said filing should file a protest with the Federal Energy Regulatory Commission, 825 North Capitol Street, NE., Washington, DC 20426, in accordance with Rule 211 of the Commission's Rules of Practice and Procedure (18 FR 385.211). All such protests must be filed on or before November 24, 1993. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Copies of this filing are on file with the Commission and are available for public inspection.

Lois D. Cashell,

Secretary.

[FR Doc. 93–28661 Filed 11–22–93; 8:45 am]

BILLING CODE 6717–01–M

[Docket No. RP91–203–036]

Tennessee Gas Pipeline Co.; Tariff Filing

November 17, 1993.

Take notice that on November 15, 1993, Tennessee Gas Pipeline Company (Tennessee) tendered for filing as part of its FERC Gas Tariff, the following tariff sheets to be effective November 1, 1993:

Fifth Revised Volume No. 1

Substitute First Revised Sheet No. 26
Substitute First Revised Sheet No. 176
Substitute Alternate First Revised Sheet No. 177
Substitute First Revised Sheet No. 178

Original Volume No. 2

Substitute Sixteenth Revised Sheet No. 9
Substitute Eighth Revised Sheet No. 9A

Tennessee states that the purpose of this filing is to comply with the Commission's October 29, 1993, order in the above-referenced docket, in order to implement the NET Settlement approved by the Commission in its order dated April 21, 1993.

Tennessee states that copies of the filing has been served on each person designated on the official service list in the above-reference proceeding.

Any person desiring to protest this filing should file a protest with the Federal Energy Regulatory Commission, 825 North Capitol Street, NE., Washington, DC 20426, in accordance with rule 211 of the Commission's Rules of Practice and Procedure. All such protest should be filed on or before November 24, 1993. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Copies of this filing are on file with the Commission and are available for public inspection.

Lois D. Cashell,

Secretary.

[FR Doc. 93–28658 Filed 11–22–93; 8:45 am]

BILLING CODE 6717–01–M

[Docket No. TM94–1–76–001]

Wyoming Interstate Co., Proposed Changes in FERC Gas Tariff

November 17, 1993.

Take notice that on November 12, 1993, Wyoming Interstate Company, Ltd. (WIC) tendered for filing as part of its FERC Gas Tariff, Second Revised Volume No. 2, Substitute First Revised Sheet No. 4, with a proposed effective date of October 1, 1993.

WIC states that it submitted tariff changes on August 20, 1993, in Docket No. TM94–1–76 to implement the

Commission's new ACA charge effective October 1, 1993. First Revised Sheet No. 4 submitted in that filing inadvertently reflected a Base Interest Component of Maximum Commodity Charge for Rate Schedule IT of $0.0000, instead of $0.0401. The instant filing corrects this error. The proposed change to Sheet No. 4 is administrative, and has no impact on the rates being billed by WIC.

WIC states copies of this filing are being served on all participants listed on the Commission's official service list in this docket.

Any person desiring to protest said filing should file a protest with the Federal Energy Regulatory Commission, 825 North Capital Street, NE., Washington, DC 20426, in accordance with § 385.211 of the Commission's Rules and Regulations. All such protests should be filed on or before November 24, 1993. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Copies of this filing are on file with the Commission and are available for public inspection in the public reference room.

Lois D. Cashell,

Secretary.

[FR Doc. 93–28663 Filed 11–22–93; 8:45 am]

BILLING CODE 6717–01–M

ENVIRONMENTAL PROTECTION AGENCY

Office of Research and Development

[FRL–4805–4]

Ambient Air Monitoring Reference and Equivalent Methods; Receipt of Two Applications for Equivalent Method Determinations

Notice is hereby given that on October 26, 1993, the Environmental Protection Agency received two applications from Lear Siegler Measurement Controls Corporation, 72 Inverness Drive East, Englewood, Colorado 80112–5189, to determine if their Monitor Labs Ozone Analyzer Models 9811 and 9812 should be designated by the Administrator of the EPA as equivalent methods under 40 CFR part 53. If, after appropriate technical study, the Administrator determines that these methods should be so designated, notice thereof will be given in a subsequent issue of the Federal Register.

Carl Gerber,

Acting Assistant Administrator for Research and Development.

[FR Doc. 93–28737 Filed 11–22–93; 8:45 am]

BILLING CODE 6560–50–M

[FRL–4805–6]

Final Maximum Pressures for Rule-Authorized Enhanced Recovery Injection Wells in Michigan—Second Group Fields

AGENCY: Environmental Protection Agency.

ACTION: Notice of Final Maximum Injection Pressure in Fields with Rule-Authorized Enhanced Recovery Injection Wells in Michigan—Second Group Fields.

SUMMARY: The United States Environmental Protection Agency (USEPA or Agency) today is issuing pressure gradients for calculating the maximum allowable liquid injection pressure for rule-authorized Class II enhanced recovery injection wells in six Michigan fields currently approved by the State of Michigan for enhanced recovery operations. Therefore, as of the date of publication of this notice, operators of rule-authorized enhanced recovery wells in the six fields must limit their liquid injection pressure as directed in this notice. This notice now becomes part of the applicable Underground Injection Control program for the State of Michigan, administered by Region 5 of USEPA, promulgated under the provisions of the Safe Drinking Water Act.

FOR FURTHER INFORMATION CONTACT: Patrick Saieh, Underground Injection Control Section, Water Division, (312) 886–4240, 17th floor Metcalfe Building (WD–17J), 77 West Jackson Boulevard, Chicago, Illinois 60604–3590.

SUPPLEMENTARY INFORMATION:

I. Background

Federal regulations at 40 CFR 147.1154 stipulate that the Regional Administrator shall establish maximum injection pressures ("field rules") for rule-authorized enhanced recovery injection wells in Michigan fields, after proper notice and opportunity for public comment. Notice was given on August 9, 1993, to persons on a state-wide mailing list and on August 10, 1993, in the Federal Register (58 FR 42543). The public notice period ended September 24, 1993. Two written comments were received, which included additional data for the West Branch and Norwich fields, respectively. The new data have been incorporated into this final notice.

II. Final Maximum Pressures

In this final notice, USEPA is announcing that rule-authorized, enhanced recovery, injection wells in the Michigan fields listed in Table 1, must operate below a maximum injection pressure for liquids calculated using the following formula:

$$Pm = (FPG - 0.433\ Sg)d$$

where

Pm = injection pressure at the wellhead (psi)

FPG = fracture pressure gradient from Table 1 (psi/ft)

Sg = specific gravity of the injection fluid (dimensionless)

d = depth to top of injection zone (ft)

III. Alternative Maximum Pressures

If an owner or operator wishes to inject at a pressure higher than that calculated using the above formula, he or she may submit a request that the USEPA establish an alternative maximum pressure for a particular field and formation. This request may result in permission to inject at higher pressures if the operator can demonstrate to the satisfaction of the Agency that the desired injection pressure will not fracture the confining layer adjacent to the lowermost Underground Source of Drinking Water (USDW) and that there will be no migration of fluids into a USDW. The Agency may grant such a request after notice and opportunity for public comment, according to the provisions of 40 CFR part 124.

If a request for an Alternative Maximum Pressure is denied, the owner or operator may apply for a UIC permit under 40 CFR 144.25(c). The final permit decision, including permit conditions which the owner or operator considers to be inappropriate, may be subject to administrative review pursuant to 40 CFR 124.19. To be added to a mailing list to receive notice of Agency decisions in Michigan regarding Alternative Maximum Pressures or Class IIR permits, contact USEPA, Region 5 Underground Injection Control Section at the address given above.

IV. Notice to Owners and Operators

Concurrent with publication of this notice, USEPA is sending certified written notices to owners and operators of wells in affected fields informing them of the applicable formula to be used in determining the maximum allowable liquid injection pressure. After receipt of this notice, owners and operators who exceed the injection pressure established under the formula or the alternative maximum pressure approved by USEPA will be considered in violation of 40 CFR 147.1154(a), and may be subject to enforcement action, including the assessment of civil penalties and the issuance of compliance orders. If an owner or

operator does not receive a certified written notice from USEPA within thirty (30) days of the date of this notice, he or she should immediately contact USEPA, Region 5 at the telephone number given above, to avoid the possibility of violating UIC regulations.

Dated: November 12, 1993.

Edward P. Watters,

Acting Director, Water Division Region 5, U.S. Environmental Protection Agency.

TABLE 1.—FRACTURE PRESSURE GRADIENT VALUES

Field	Formation	County	Township/range/section	FPG (psi/ft)
Enterprise	Richfield	Missaukee	T23N,R4W,S18 and T23N,R5W,S10–14	1.10
Hamilton	Richfield	Clare	T19N,R3W,S5–8 and T19N,R4W,S1,2 and T20N,R4W,S35,36	1.06
Manistee	Niagaran	Manistee	T22N,R17W,S36	0.82
East Norwich	Richfield	Missaukee	T24N,R5W,S1–3,9–16, 21, 22 and T24N,R4W,S6,7,18	1.14
St. Helen	Richfield	Roscommon	T24N,R1W,S16,19–21,27–30	1.16
West Branch	Dundee	Ogewmaw.		
West Branch Unit	.....	.....	T21N,R2E,S2 and T22N,R2E,S21,26,27,33–36 and all of S28 except the S/2 of the NW/4*.	1.15
Country Club Unit.	.....	.....	T22N,R1E,S13,24 and T22N,R2E,S18–21,29	1.15

* Pressure limits for the S/2 of the NW/4 of Section 28, the "West Branch 28 Unit", will be proposed and finalized with the third group of fields.

[FR Doc. 93–28735 Filed 11–22–93; 8:45 am]
BILLING CODE 6560–50–P

[FRL 4805–2]

Ambient Water Quality Criteria Aniline and 2,4-Dimethylphenol

AGENCY: Environmental Protection Agency.

ACTION: Notice of availability and request for comments on Proposed Ambient Water Quality Criteria Documents for the Protection of Aquatic Life.

SUMMARY: The purpose of the notice is to announce the availability of two documents presenting proposed Ambient Water Quality Criteria for the protection of aquatic life for two chemicals; and to request public comment on these documents. The documents present data and proposed criteria for aniline and 2,4-dimethylphenol. The Environmental Protection Agency (EPA) intends to publish the documents in final form after considering public comments. This action is taken pursuant to section 304(a)(1) of the Clean Water Act, which requires EPA to develop and publish criteria for water quality accurately reflecting the latest scientific knowledge. When published in final form these criteria will serve as guidance to States in developing water quality standards, which are used as the basis for establishing enforceable water quality based effluent limitations.

DATES: Written comments should be submitted on or before January 24, 1994, and should be addressed as indicated below.

ADDRESSES: Requests for documents should be sent to: Aniline and 2,4-Dimethylphenol Proposal, Water Resource Center, (RC–4100), U.S. Environmental Protection Agency, 401 M Street, SW., Washington, DC 20460.

Send written comments on the draft documents to: Aniline and 2,4-Dimethylphenol Proposal, Comment Clerk; Water Docket (MC–4101), U.S. Environmental Protection Agency, 401 M Street, SW., Washington, DC 20460.

Commenters are requested to submit any references cited in their comments. Commenters are also requested to submit an original and 3 copies of their written comments and enclosures. Commenters who want receipt of their comments acknowledged should include a self-addressed, stamped envelope. No facsimiles (faxes) will be accepted.

FOR FURTHER INFORMATION CONTACT: Call Ecological Risk Assessment Branch at (202) 260–0658.

Availability of Documents

This notice announces the availability of draft documents proposing Ambient Water Quality Criteria for the protection of aquatic life for two chemicals. EPA is releasing the following draft criteria documents for public review and comments:

* Ambient Aquatic Life Water Quality Criteria for ANILINE.
* Ambient Aquatic Life Water Quality Criteria for 2,4-DIMETHYLPHENOL.

Acute and Chronic Criteria for the protection of aquatic life within proposed "Ambient Aquatic Life Water Quality Criteria for 2,4-DIMETHYLPHENOL" would, upon finalization, supersede guidance given in the previous Ambient Water Quality Criteria for 2,4-dimethylphenol (U.S. EPA, 1980). The proposed criteria were derived using improved procedures and additional information.

Copies of the complete drafts may be obtained upon request by writing to the address listed above. These documents are available for review at EPA's Water Docket; 401 M Street, SW., Washington, DC 20460. For access, call (202) 260–3027 between 9 am and 3:30 pm for an appointment. Copies of these documents are also available for review in the EPA Regional Office libraries. As provided in 40 CFR part 2, a reasonable fee may be charged for copying services.

Background Information

Section 304(a)(1) of the Clean Water Act (33 U.S.C. 1314(a)(1)), directs EPA to develop and publish criteria reflecting the latest scientific knowledge on the identifiable effects of pollutants on public health and welfare, aquatic life and recreation.

The draft criteria announced today are intended to protect aquatic life and were derived using the 1985 "Guidelines for Deriving Numerical National Water Quality Criteria for the Protection of Aquatic Organisms and Their Uses" (50 FR 30784). All of the criteria developed by EPA using this methodology are summarized in Quality Criteria for Water 1986 (1986 "Gold Book") (which is updated periodically).

EPA's criteria documents provide a comprehensive aquatic toxicological evaluation of each chemical. For toxic pollutants, the documents tabulate the relevant acute and chronic toxicity information for aquatic life and derive the criteria maximum concentrations (acute criteria) and criteria continuous

concentrations (chronic criteria) which the Agency recommends to protect aquatic life resources. The proposed criteria announced today are not intended to protect human health and do not address human health concerns.

Description of Pollutants and Associated Criteria

Criteria pollutants were selected based on two factors: (1) frequency of occurrence in the environment; and (2) availability of existing toxicological data for each chemical. Those toxic pollutants which are given high priority by EPA's Office of Water, as described in section 307(a) of the Clean Water Act and listed in 40 CFR part 423, appendix A, were also considered.

Aniline

(CAS Registry No. 62–53–3)

Aniline (aminobenzene, benzenamine, phenylamine) occurs naturally in coal tars and is manufactured through various chemical procedures. The major uses of aniline are in the polymer, rubber, agricultural and dye industries. Aniline is used to manufacture polyurethanes, antioxidants, antidegradants, vulcanization accelerators, and sulfa drugs. Aniline derivatives are used in herbicides, fungicides, insecticides, repellents, and defoliants. Aniline has also been used as an antiknock compound in gasolines. Aniline is the simplest of the aromatic amines ($C_6H_5NH_2$).

2,4-Dimethylphenol

(CAS Registry No. 105–67–9)

2,4-Dimethylphenol (2,4-DMP) is a naturally occurring, substituted phenol derived from petroleum or coal tars. 2,4-DMP (1-hydroxy-2,2-dimethylbenzene, m-xylenol, 2,4-xylenol or m-4-xylenol) is used in the manufacture of phenolic antioxidants, disinfectants, solvents, pharmaceuticals, insecticides, fungicides, plasticizers, rubber chemicals, polyphenylene oxide, wetting agents, and dyestuffs. 2,4-DMP is also an additive of lubricants, gasolines, and cresylic acid.

Pollutant	CWA 307(a) priority pollutant?	Proposed FW acute criterion	Proposed SW acute criterion	Proposed FW chronic criterion	Proposed SW chronic criterion
Aniline	No	14 µg/L	77 µg/L	6.7 µg/L	37 µg/L.
2,4-dimethylphenol	Yes	1,300 µg/L	270 µg/L	530 µg/L	110 µg/L.

Request for Comments

EPA is soliciting comments on the proposed criteria documents. If issued in final form, the proposed documents would supersede material specific to the aquatic life toxicity of these chemicals as published in any previous ambient water quality criteria documents. Specifically, Acute and Chronic Criteria for the protection of aquatic life within proposed "Ambient Aquatic Life Water Quality Criteria for 2,4-Dimethylphenol" would, upon finalization, supersede guidance given in the previous Ambient Water Quality Criteria for 2,4-dimethylphenol (U.S. EPA, 1980). The proposed criteria were derived using improved procedures and additional information.

The Agency is soliciting additional toxicological data on the pollutants covered by today's notice. Data suitable (as specified in the Agency's guidelines for developing aquatic life criteria) for determining the bioconcentration of Aniline in freshwater (FW) or saltwater (SW) organisms is of particular interest. The Agency is also soliciting comments on the scientific basis for the criteria values, the appropriate analytical techniques for measuring attainment of criteria, and the allowable duration and frequency for exceeding the criteria. The proposed criteria announced today, if published in final form, would serve as guidance to the States in developing water quality standards pursuant to 40 CFR part 131.

Dated: November 11, 1993.

Robert Perciasepe,

Assistant Administrator for Water.

[FR Doc. 93–28738 Filed 11–22–93; 8:45 am]

BILLING CODE 6560–50–M

EXPORT-IMPORT BANK

Advisory Committee; Meeting

SUMMARY: The Advisory Committee was established by Public Law 98–181, November 30, 1983, to advise the Export-Import Bank on its programs and to provide comments for inclusion in the reports of the Export-Import Bank to the United States Congress.

TIME AND PLACE: Tuesday, December 7, 1993, from 9:30 a.m. to 12 noon. The meeting will be held at Eximbank in room 1143, 811 Vermont Avenue, NW., Washington, DC 20571.

AGENDA: The meeting agenda will include a discussion of the following topics: Advisory Committee Comments on Lundine/Key Linkages Report; Subcommittee Reports: Small Business, Banking, Insurance, Project Finance, CIS/Eastern Europe, Tied Aid; and other topics.

PUBLIC PARTICIPATION: The meeting will be open to public participation; and the last 10 minutes will be set aside for oral questions or comments. Members of the public may also file written statement(s) before or after the meeting. In order to permit the Export-Import Bank to arrange suitable accommodations, members of the public who plan to attend the meeting should notify Loretta Carrier, room 1112, 811 Vermont Avenue, NW., Washington, DC 20571, (202) 566–8893, not later than December 6, 1993. If any person wishes auxiliary aids (such as a sign language interpreter) or other special accommodations, please contact, prior to December 2, 1993, Loretta Carrier, room 1112, 811 Vermont Avenue, NW., Washington, DC 20571, Voice: (202) 566–8893 or TDD: (202) 535–3913.

FOR FURTHER INFORMATION CONTACT: For further information, contact Loretta Carrier, room 1112, 811 Vermont Avenue, NW., Washington, DC 20571, (202) 566–8893.

Helene H. Wall,

Vice President, Administrative & Management Services.

[FR Doc. 93–28723 Filed 11–22–93; 8:45 am]

BILLING CODE 6690–01–M

FEDERAL COMMUNICATIONS COMMISSION

[Report No. 1985]

Application for Review of Action in Rulemaking Proceeding

November 10, 1993.

Application for review has been filed in the Commission rulemaking proceeding listed in this Public Notice and published pursuant to 47 CFR 1.429(e). The full text of this document is available for viewing and copying in room 239, 1919 M Street, NW., Washington, DC or may be purchased from the Commission's copy contractor ITS, Inc., (202) 857–3800. Opposition to

this petition must be filed December 8, 1993. See § 1.4(b)(1) of the Commission's rules (47 CFR 1.4(b)(1)). Replies to an opposition must be filed within 10 days after the time for filing oppositions has expired.

Subject: Amendment of § 73.202(b) FM Table of Allotments FM Broadcast Stations (Kingsville and Ingleside, Texas) (MM Docket No. 88–257).

Application for Review

Number of Petitions Filed: 1.

Federal Communications Commission

William F. Caton,

Acting Secretary.

[FR Doc. 93–28644 Filed 11–22–93; 8:45 am]

BILLING CODE 6712–01–M

FEDERAL MARITIME COMMISSION

[Petition No. P95–93]

Petition for Temporary Exemption From Electronic Tariff Filing Requirements; Petition of Yangming Marine Transport Corporation; Filing of Petition

Notice is hereby given of the filing of a petition by Yangaming Marine Transport Corporation pursuant to 46 CFR 514.8(a), for temporary exemption from the November 22, 1993, electronic service contract tariff filing requirements of the Commission's ATFI System.

To facilitate thorough consideration of the petition, interested persons are requested to reply to the petition no later than November 26, 1993. Replies shall be directed to the Secretary, Federal Maritime Commission, Washington, DC 20573–0001, shall consist of an original and 15 copies, and shall be served on Counsel for petitioner, Paul M. Keane, Esq., Cichanowicz, Callan & Keane, 21 West Street, New York, New York 10006–2908.

Copies of the petition are available for examination at the Washington, DC office of the Secretary of the Commission, 800 North Capitol Street, NW., room 1046.

Joseph C. Polking,

Secretary.

[FR Doc. 93–28638 Filed 11–22–93; 8:45 am]

BILLING CODE 6730–01–M

FEDERAL RESERVE SYSTEM

BB&T Financial Corporation, et al.; Formations of; Acquisitions by; and Mergers of Bank Holding Companies

The companies listed in this notice have applied for the Board's approval under section 3 of the Bank Holding Company Act (12 U.S.C. 1842) and § 225.14 of the Board's Regulation Y (12 CFR 225.14) to become a bank holding company or to acquire a bank or bank holding company. The factors that are considered in acting on the applications are set forth in section 3(c) of the Act (12 U.S.C. 1842(c)).

Each application is available for immediate inspection at the Federal Reserve Bank indicated. Once the application has been accepted for processing, it will also be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing to the Reserve Bank or to the offices of the Board of Governors. Any comment on an application that requests a hearing must include a statement of why a written presentation would not suffice in lieu of a hearing, identifying specifically any questions of fact that are in dispute and summarizing the evidence that would be presented at a hearing.

Unless otherwise noted, comments regarding each of these applications must be received not later than December 17, 1993.

A. Federal Reserve Bank of Richmond (Lloyd W. Bostian, Jr., Senior Vice President) 701 East Byrd Street, Richmond, Virginia 23261:

1. BB&T Financial Corporation, Wilson, North Carolina; to acquire 100 percent of the voting shares of Asheville Savings Bank, SSB, Asheville, North Carolina.

B. Federal Reserve Bank of St. Louis (Randall C. Sumner, Vice President) 411 Locust Street, St. Louis, Missouri 63166:

1. Sun Financial Corporation, Earth City, Missouri; to acquire at least 84.45 percent of the voting shares of Farmers State Bank of Risco, Risco, Missouri.

C. Federal Reserve Bank of Minneapolis (James M. Lyon, Vice President) 250 Marquette Avenue, Minneapolis, Minnesota 55480:

1. Elmore Bancshares, Inc., Elmore, Minnesota; to acquire at least 83.2 percent of the voting shares of Farmers State Bank of Delavan, Delavan, Minnesota.

D. Federal Reserve Bank of Kansas City (John E. Yorke, Senior Vice President) 925 Grand Avenue, Kansas City, Missouri 64198:

1. Community Banks of Kansas, Inc., Prairie Village, Kansas; to become a bank holding company by acquiring 100 percent of the voting shares of First Kansas Holding Company, Junction City, Kansas, and thereby indirectly acquire First State Bank, Junction City, Kansas, and to acquire 99.18 percent of the voting shares of Chapman Bancshares, Inc., Prairie Village, Kansas, and thereby indirectly acquire Community Bank, Chapman, Kansas.

2. Lindoe, Inc., Ordway, Colorado; to acquire 100 percent of the voting shares of Pueblo Bancorporation, Inc., Pueblo, Colorado, and thereby indirectly acquire Pueblo Bank & Trust Company, Pueblo, Colorado.

3. Southwest Kansas Bancshares, Inc., Girard, Kansas; to become a bank holding company by acquiring 99 percent of the voting shares of Prescott State Bank Holding Company, Prescott, Kansas, and thereby indirectly acquire Prescott State Bank, Prescott, Kansas.

Board of Governors of the Federal Reserve System, November 17, 1993.

Jennifer J. Johnson,

Associate Secretary of the Board.

[FR Doc. 93-28687 Filed 11-22-93; 8:45 am]

BILLING CODE 6210-01-F

Dauphin Deposit Corporation, et al.; Notice of Applications to Engage de novo in Permissible Nonbanking Activities

The companies listed in this notice have filed an application under § 225.23(a)(1) of the Board's Regulation Y (12 CFR 225.23(a)(1)) for the Board's approval under section 4(c)(8) of the Bank Holding Company Act (12 U.S.C. 1843(c)(8)) and § 225.21(a) of Regulation Y (12 CFR 225.21(a)) to commence or to engage *de novo*, either directly or through a subsidiary, in a nonbanking activity that is listed in § 225.25 of Regulation Y as closely related to banking and permissible for bank holding companies. Unless otherwise noted, such activities will be conducted throughout the United States.

Each application is available for immediate inspection at the Federal Reserve Bank indicated. Once the application has been accepted for processing, it will also be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing on the question whether consummation of the proposal can "reasonably be expected to produce benefits to the public, such as greater convenience, increased competition, or gains in efficiency, that outweigh possible adverse effects, such as undue concentration of resources, decreased or unfair competition, conflicts of interests, or unsound banking practices." Any request for a hearing on this question must be accompanied by a statement of the reasons a written presentation would not suffice in lieu of a hearing, identifying specifically any questions of fact that are in dispute, summarizing the

evidence that would be presented at a hearing, and indicating how the party commenting would be aggrieved by approval of the proposal.

Unless otherwise noted, comments regarding the applications must be received at the Reserve Bank indicated or the offices of the Board of Governors not later than December 13, 1993.

A. Federal Reserve Bank of Philadelphia (Thomas K. Desch, Vice President) 100 North 6th Street, Philadelphia, Pennsylvania 19105:

1. Dauphin Deposit Corporation, Harrisburg, Pennsylvania; to engage *de novo* through its subsidiary, Farmers Maryland, Inc., Owings Mills, Maryland, in soliciting loans pursuant to § 225.25(b)(1) of the Board's Regulation Y.

B. Federal Reserve Bank of Richmond (Lloyd W. Bostian, Jr., Senior Vice President) 701 East Byrd Street, Richmond, Virginia 23261:

1. City Holding Company, Charleston, West Virginia; to engage *de novo* through its subsidiary, City Mortgage Corporation, McKee's Rocks, Pennsylvania, in making, acquiring, or servicing loans or other extensions of credit (including issuing letters of credit and accepting drafts) for Company's account and the account of others; performing real estate appraisals; performing loan settlement services; and offering, as agent or broker, insurance (including home mortgage redemption insurance) that is (i) directly related to extensions of credit by Company or its affiliates and (ii) limited to assuring the repayment of the outstanding balance due on such extension of credit in the event of the death, disability or involuntary unemployment of the debtor pursuant to §§ 225.25(b)(1)(ii), (b)(8), and (b)(13) of the Board's Regulation Y.

C. Federal Reserve Bank of Atlanta (Zane R. Kelley, Vice President) 104 Marietta Street, N.W., Atlanta, Georgia 30303:

1. SunTrust Banks, Inc., Atlanta, Georgia; to engage *de novo* through its subsidiary, SunTrust Securities, Inc., Atlanta, Georgia, in providing financial advice, arranging commercial real estate equity financing and providing securities brokerage services pursuant to §§ 225.25(b)(4)(iii), (iv), (v), and (vi), (b)(14) and (b)(15)(ii) of the Board's Regulation Y.

D. Federal Reserve Bank of Chicago (James A. Bluemle, Vice President) 230 South LaSalle Street, Chicago, Illinois 60690:

1. First Midwest Bancorp, Inc., Naperville, Illinois; to engage *de novo* through its subsidiary, First Midwest Mortgage, Inc., Joliet, Illinois, in making, acquiring, selling and servicing residential mortgage loans pursuant to § 225.25(b)(1) of the Board's Regulation Y, and to acquire certain assets of the mortgage operations of its subsidiary banks including the mortgage servicing rights and the mortgage loans held for sale.

2. Weldon Bancshares, Inc., Weldon, Illinois; to engage *de novo* through its subsidiary, Weldon Insurance Service, Weldon, Illinois, in general insurance agency activities in a town with a population of less than 5,000 pursuant to § 225.25(b)(8)(iii) of the Board's Regulation Y. These activities will be conducted in Weldon, Illinois.

Board of Governors of the Federal Reserve System, November 17, 1993.

Jennifer J. Johnson,

Associate Secretary of the Board.

[FR Doc. 93-28693 Filed 11-22-93; 8:45 am]

BILLING CODE 6210-01-F

Hawkeye Bancorporation, et al.; Acquisitions of Companies Engaged in Permissible Nonbanking Activities

The organizations listed in this notice have applied under § 225.23(a)(2) or (f) of the Board's Regulation Y (12 CFR 225.23(a)(2) or (f)) for the Board's approval under section 4(c)(8) of the Bank Holding Company Act (12 U.S.C. 1843(c)(8)) and § 225.21(a) of Regulation Y (12 CFR 225.21(a)) to acquire or control voting securities or assets of a company engaged in a nonbanking activity that is listed in § 225.25 of Regulation Y as closely related to banking and permissible for bank holding companies. Unless otherwise noted, such activities will be conducted throughout the United States.

Each application is available for immediate inspection at the Federal Reserve Bank indicated. Once the application has been accepted for processing, it will also be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing on the question whether consummation of the proposal can "reasonably be expected to produce benefits to the public, such as greater convenience, increased competition, or gains in efficiency, that outweigh possible adverse effects, such as undue concentration of resources, decreased or unfair competition, conflicts of interests, or unsound banking practices." Any request for a hearing on this question must be accompanied by a statement of the reasons a written presentation would not suffice in lieu of a hearing, identifying specifically any questions of fact that are in dispute, summarizing the evidence that would be presented at a hearing, and indicating how the party commenting would be aggrieved by approval of the proposal.

Unless otherwise noted, comments regarding each of these applications must be received at the Reserve Bank indicated for the application or the offices of the Board of Governors not later than December 17, 1993.

A. Federal Reserve Bank of Chicago (James A. Bluemle, Vice President) 230 South LaSalle Street, Chicago, Illinois 60690:

1. Hawkeye Bancorporation, Des Moines, Iowa; to acquire Centre Pointe Leasing Co., Inc., West Des Moines, Iowa, and thereby engage in nonoperating leasing activities pursuant to § 225.25(b)(5) of the Board's Regulation Y.

B. Federal Reserve Bank of Kansas City (John E. Yorke, Senior Vice President) 925 Grand Avenue, Kansas City, Missouri 64198:

1. Pinnacle Bancorp, Inc., Central City, Nebraska, through its proposed subisdiary, Pinnacle Investment Company, Windsor, Colorado; to enter into a joint venture with Gilbert Marshall and Company, Greeley, Colorado, by acquiring 81 percent of Pinnacle Financial Services, Windsor, Colorado, and thereby engage in providing full service brokerage services pursuant to § 225.25(b)(15) of the Board's Regulation Y.

Board of Governors of the Federal Reserve System, November 17, 1993.

Jennifer J. Johnson,

Associate Secretary of the Board.

[FR Doc. 93-28690 Filed 11-22-93; 8:45 am]

BILLING CODE 6210-01-F

The Sumitomo Bank, Limited, Osaka, Japan; Application to Engage in Nonbanking Activities

The Sumitomo Bank, Limited, Osaka, Japan (Applicant), has applied pursuant to section 4(c)(8) of the Bank Holding Company Act (12 U.S.C. 1843(c)(8)) (BHC Act) and § 225.23(a)(3) of the Board's Regulation Y (12 CFR 225.23(a)(3)) to engage *de novo* through its subsidiary, Sumitomo Bank Capital Markets, Inc. (Company), in providing by any means general information and statistical forecasting with respect to foreign exchange markets; advisory services designed to assist customers in monitoring, evaluating, and managing their foreign exchange exposures; and transactional services with respect to foreign exchange by arranging for swaps among customers with complementary foreign exchange transactions.

Section 4(c)(8) of the BHC Act provides that a bank holding company may, with Board approval, engage in any activity which the Board, after due notice and opportunity for hearing, has determined (by order or regulation) to be so closely related to banking or managing or controlling banks as to be a proper incident thereto. This statutory test requires that two separate tests be met for an activity to be permissible for a bank holding company. First, the Board must determine that the activity is, as a general matter, closely related to banking. Second, the Board must find in a particular case that the performance of the activity by the applicant bank holding company may reasonably be expected to produce public benefits that outweigh possible adverse effects.

A particular activity may be found to meet the "closely related to banking" test if it is demonstrated that banks have generally provided the proposed activity; that banks generally provide services that are operationally or functionally similar to the proposed activity so as to equip them particularly well to provide the proposed activity; or that banks generally provide services that are so integrally related to the proposed activity as to require their provision in a specialized form. *National Courier Ass'n v. Board of Governors*, 516 F.2d 1229, 1237 (DC Cir. 1975). In addition, the Board may consider any other basis that may demonstrate that the activity has a reasonable or close relationship to banking or managing or controlling banks. Board Statement Regarding Regulation Y, 49 FR 806 (1984).

The Board previously has determined that the proposed foreign exchange advisory and transactional services are closely related to banking within the meaning of section 4(c)(8) of the BHC Act when conducted subject to certain specified conditions and limitations. *See* 12 CFR 225.25(b)(17). One of those conditions is that the company engaged in the foreign exchange activities does not take positions in foreign exchange for its own account; another of those conditions is that the company does not itself execute foreign exchange transactions. *See* 12 CFR 225.25(b)(17)(i), (iii).

Company engages in currency swap and swap-related transactions, and, in connection with such swap transactions, takes positions in foreign currency and executes foreign currency transactions. *See The Sumitomo Bank, Limited*, 75 Federal Reserve Bulletin 582 (1989). These activities would preclude Sumitomo from conducting the proposed foreign exchange activities strictly in accordance with the conditions and limitations specified in § 225.25(b)(17). To address the concerns raised by the conduct of Sumitomo's existing currency swap activities concurrently with the proposed foreign exchange activities, Sumitomo proposes to disclose to customers transactions in which Company may have an interest, and to offer its currency advisory and transactional services only to sophisticated customers who would be unlikely to place undue reliance on investment advice received and would be better able to detect investment advice motivated by self-interest. Applicant believes that these limitations adequately address any possible concerns that might arise when a bank holding company provides foreign exchange advisory and transactional services while concurrently taking positions and executing transactions in foreign currencies.

In order to satisfy the proper incident to banking test, section 4(c)(8) of the BHC Act requires the Board to find that the performance of the activities by Company can reasonably be expected to produce benefits to the public, such as greater convenience, increased competition, or gains in efficiency that outweigh possible adverse effects, such as undue concentration of resources, decreased or unfair competition, conflicts of interest, or unsound banking practices. Applicant believes that the proposed activities will benefit the public by promoting competition. Applicant believes that the proposed activities will not result in any unsound banking practices or other adverse effects.

In publishing the proposal for comment, the Board does not take a position on issues raised by the proposal. Notice of the proposal is published solely in order to seek the views of interested persons on the issues presented by the application and does not represent a determination by the Board that the proposal meets, or is likely to meet, the standards of the BHC Act.

Any comments or requests for hearing should be submitted in writing and received by William W. Wiles, Secretary, Board of Governors of the Federal Reserve System, Washington, D.C. 20551, not later than December 15, 1993. Any request for a hearing on this application must, as required by § 262.3(e) of the Board's Rules of Procedure (12 CFR 262.3(e)), be accompanied by a statement of the reasons why a written presentation would not suffice in lieu of a hearing, identifying specifically any questions of fact that are in dispute, summarizing the evidence that would be presented at a hearing, and indicating how the party commenting would be aggrieved by approval of the proposal.

This application may be inspected at the offices of the Board of Governors or the Federal Reserve Bank of San Francisco.

Board of Governors of the Federal Reserve System, November 17, 1993.

Jennifer J. Johnson,

Associate Secretary of the Board.

[FR Doc. 93-28689 Filed 11-22-93; 8:45 am]

BILLING CODE 6210-01-F

G.E. Wortman, et al.; Change in Bank Control Notices; Acquisitions of Shares of Banks or Bank Holding Companies

The notificants listed below have applied under the Change in Bank Control Act (12 U.S.C. 1817(j)) and § 225.41 of the Board's Regulation Y (12 CFR 225.41) to acquire a bank or bank holding company. The factors that are considered in acting on the notices are set forth in paragraph 7 of the Act (12 U.S.C. 1817(j)(7)).

The notices are available for immediate inspection at the Federal Reserve Bank indicated. Once the notices have been accepted for processing, they will also be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing to the Reserve Bank indicated for that notice or to the offices of the Board of Governors. Comments must be received not later than December 13, 1993.

A. Federal Reserve Bank of Kansas City (John E. Yorke, Senior Vice President) 925 Grand Avenue, Kansas City, Missouri 64198:

1. G.E. Wortman, Loup City, Nebraska; to acquire an additional 11.51 percent of the voting shares of Sherman County Management, Inc., Loup City, Nebraska, for a total of 23.85 percent, and thereby indirectly acquire Sherman County Bank, Loup City, Nebraska.

B. Federal Reserve Bank of Dallas (Genie D. Short, Vice President) 2200 North Pearl Street, Dallas, Texas 75201-2272:

1. Albert Furman, Glenview, Illinois, to acquire 45.4 percent; Robert Cook, Union Grove, Wisconsin, to acquire 7.6 percent; Robert Durham, Austin, Texas, to acquire 7.6 percent; Howard Marvin, Palm Desert, California, to acquire 7.6 percent; and Robert Wunsch, Austin, Texas, to acquire 7.6 percent of the voting shares of Hutto State Bank, Hutto, Texas.

Board of Governors of the Federal Reserve System, November 17, 1993.

Jennifer J. Johnson,

Associcte Secretary of the Board.

[FR Doc. 93-28688 Filed 11-22-93; 8:45 am]

BILLING CODE 6210-01-F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Idaho National Engineering Laboratory Environmental Dose Reconstruction Project: Public Meeting

The National Center for Environmental Health (NCEH), Centers for Disease Control and Prevention (CDC), announces the following meeting.

Name: Initiation of Sanford Cohen and Associates' Working Group for the Idaho Engineering Laboratory Environmental Dose Reconstruction Project.

Time and Date: 6:30 p.m.–9 p.m., Monday, December 13, 1993.

Place: Red Lion-Riverside, 2900 Chinden Boulevard, Boise, Idaho 83714.

Status: Open to the public for observation and comment, limited only by space available. The meeting room will accommodate approximately 100 people.

Purpose: Under a Memorandum of Understanding with the Department of Energy (DOE), the Department of Health and Human Services has been given the responsibility and resources for conducting analytic epidemiologic investigations of residents of communities in the vicinity of DOE facilities and other persons potentially exposed to radiation or to potential hazards from non-nculear energy production and use.

An initial step in an analytic epidemiologic study for persons living offsite of a given DOE facility is the reconstruction of radiation doses due to releases from that facility. CDC has begun such an environmental dose reconstruction for DOE's Idaho National Engineering Laboratory near Idaho Falls, Idaho. Sanford Cohen & Associates (SC&A) is gathering the data necessary to perform the dose reconstruction under contract to CDC. SC&A is forming a working group made up of Idaho citizens. The working group's primary purpose will be to follow the project's progress and provide input in SC&A's planning process. The purpose of this public meeting is to:

(1) Initiate the working group for SC&A;

(2) Provide the public an opportunity to review actual records that have been entered into the database;

(3) Discuss topics of future meetings; and

(4) Solicit any additional comments from the public regarding the Environmental Dose Reconstruction Project.

Agenda items are subject to change as priorities dictate.

Contact person for More Information: Leeann S. Denham, Radiation Studies Branch, Division of Environmental Hazards and Health Effects, NCEH, CDC, 4770 Buford Highway NE., (F–35), Atlanta, Georgia, 30341–3724, telephone 404/488–7040.

Dated: November 16, 1993.

Elvin Hilyer,

Associate Director for policy Coordination, Centers for Disease Control and Prevention (CDC).

[FR Doc. 93–28682 Filed 11–22–93; 8:45 am]

BILLING CODE 4160–18–M

Workshop on a Strategy for Power Hand Tool Ergonomics Research—Design, Selection, Installation, and Use Within the Automotive Industry: Meeting

The National Institute for Occupational Safety and Health (NIOSH) of the Centers for Disease Control and Prevention (CDC) announces the following meeting.

Name: Workshop on a Strategy for Power Hand Tool Ergonomics Research—Design, Selection, Installation, and Use Within the Automotive Industry.

Times and Dates: 9:15 a.m.–3 p.m., January 13, 1994. 9 a.m.–12 noon, January 14, 1994.

Place: Alice Hamilton Laboratory, Conference Room C, NIOSH, CDC, 5555 Ridge Avenue, Cincinnati, Ohio 45226.

Status: Open to the public, limited only by the space available.

Purpose: The purpose of this meeting is to identify the power hand tools utilized in the automotive manufacturing industry, problems associated with power hand tool usage, and the existing research in the area of adverse biomechanical and physiological effects from power hand tools. Using this information to determine research gaps, discussions of strategies for filling specific gaps will be conducted. Three areas for discussion will be emphasized at the Workshop—Surveillance/Epidemiology, Problem Source Identification, and Engineering Controls and Design/Manufacturing. Viewpoints and suggestions from industry, labor, academia, other government agencies, and the public are invited.

Contact Person for Additional Information: Steve Smith, NIOSH, CDC, 4676 Columbia Parkway, Mailstop R5, Cincinnati, Ohio 45226, telephone 513/841–4385.

Dated: November 16, 1993.

Elvin Hilyer,

Associate Director for Policy Coordination, Centers for Disease Control and Prevention (CDC).

[FR Doc. 93–28681 Filed 11–22–93; 8:45 am]

BILLING CODE 4160–19–M

Health Resources and Services Administration

National Vaccine Injury Compensation Program; List of Petitions Received

AGENCY: Public Health Service, HHS.

ACTION: Notice.

SUMMARY: The Public Health Service (PHS) is publishing this notice of petitions received under the National Vaccine Injury Compensation Program ("the Program"), as required by section 2112(b)(2) of the PHS Act, as amended. While the Secretary of Health and Human Services is named as the respondent in all proceedings brought by the filing of petitions for compensation under the Program, the United States Court of Federal Claims is charged by statute with responsibility for considering and acting upon the petitions.

FOR FURTHER INFORMATION CONTACT: For information about requirements for filing petitions, and the Program generally, contact the Clerk, United States Court of Federal Claims, 717 Madison Place NW., Washington, DC. 20005, (202) 219–9657. For information on the Public Health Service's role in the Program, contact the Administrator, Vaccine Injury Compensation Program, 6001 Montrose Road, room 702, Rockville, MD 20852, (301) 443–6593.

SUPPLEMENTARY INFORMATION: The Program provides a system of no-fault compensation for certain individuals who have been injured by specified childhood vaccines. Subtitle 2 of title XXI of the PHS Act, 42 U.S.C. 300aa-10 *et seq*, provides that those seeking compensation are to file a petition with the U.S. Court of Federal Claims and to serve a copy of the petition on the Secretary of Health and Human Services, who is named as the respondent in each proceeding. The Secretary has delegated his responsibility under the Program to PHS. The Court is directed by statute to appoint special masters who take evidence, conduct hearings as appropriate, and make initial decisions as to eligibility for, and amount of, compensation.

A petition may be filed with respect to injuries, disabilities, illnesses, conditions, and deaths resulting from vaccines described in the Vaccine Injury Table set forth at section 2114 of the PHS Act. This Table lists for each covered childhood vaccine the conditions which will lead to compensation and, for each condition, the time period for occurrence of the first symptom or manifestation of onset or of significant aggravation after vaccine administration. Compensation may also be awarded for conditions not listed in the Table and for conditions that are manifested after the time periods specified in the Table, but only if the petitioner shows that the

condition was caused by one of the listed vaccines.

Section 2112(b)(2) of the PHS Act, 42 U.S.C. 300aa-12(b)(2), requires that the Secretary publish in the **Federal Register** a notice of each petition filed. Set forth below is a partial list of petitions received by PHS on October 1, 1990.

Section 2112(b)(2) also provides that the special master "shall afford all interested persons an opportunity to submit relevant, written information" relating to the following:

1. The existence of evidence "that there is not a preponderance of the evidence that the illness, disability, injury, condition, or death described in the petition is due to factors unrelated to the administration of the vaccine described in the petition," and

2. Any allegation in a petition that the petitioner either:

(a) "Sustained, or had significantly aggravated, any illness, disability, injury, or condition not set forth in the Vaccine Injury Table (see section 2114 of the PHS Act) but which was caused by" one of the vaccines referred to in the table, or

(b) "Sustained, or had significantly aggravated, any illness, disability, injury, or condition set forth in the Vaccine Injury Table the first sympton or manifestation of the onset or significant aggravation of which did not occur within the time period set forth in the Table but which was caused by a vaccine" referred to in the Table.

This notice will also serve as the special master's invitation to all interested persons to submit written information relevant to the issues described above in the case of the petitions listed below. Any person choosing to do so should file an original and three (3) copies of the information with the Clerk of the U.S. Court of Federal Claims at the address listed above (under the heading "For Further Information Contact"), with a copy to PHS addressed to Director, Bureau of Health Professions, 5600 Fishers Lane, room 8–05, Rockville, MD 20857. The Court's caption (*Petitioner's Name* v. *Secretary of Health and Human Services*) and the docket number assigned to the petition should be used as the caption for the written submission.

Chapter 35 of title 44, United States Code, related to paperwork reduction, does not apply to information required for purposes of carrying out the Program.

List of Petitions

1. Tyne Gonzales on behalf of Brian Gonzales, El Paso, Texas, Claims Court Number 90–3626 V
2. Vickie Leonard, Baton Rouge, Louisiana, Claims Court Number 90–3627 V
3. Helena Howard, Elaine, Arkansas, Claims Court Number 90–3628 V
4. Patrick Tynan, Shreveport, Louisiana, Claims Court Number 90–3629 V
5. Eva Mitchell on behalf of Janice Majewski, Paola, Kansas, Claims Court Number 90–3630 V
6. James K. and Susan Lautenbacher on behalf of James H. Lautenbacher, Orange, New Jersey, Claims Court Number 90–3631 V
7. Joseph and Cynthia Lamb on behalf of Stephanie Lamb, Fort Lauderdale, Florida, Claims Court Number 90–3633 V
8. Robert and Linda Rowe, Jr., on behalf of Daniel Rowe, Sewickley, Pennsylvania, Claims Court Number 90–3634 V
9. Janice Baresel on behalf of James Baresel, Bayport, New York, Claims Court Number 90–3635 V
10. William Shamrell on behalf of Bernadette Shamrell, Deceased, San Gabriel, California, Claims Court Number 90–3636 V
11. Lillie Nusz on behalf of Robert and Stanley Nusz, Enid, Oklahoma, Claims Court Number 90–3637 V
12. Linda Young, Mt. Pleasant, Iowa, Claims Court Number 90–3638 V
13. Brenda Klein on behalf of Sharon Giardina and Karen Klein, Greer, South Carolina, Claims Court Number 90–3639 V
14. Martin Fields on behalf of Martin Fields, Jr., Deceased, Norfolk, Virginia, Claims Court Number 90–3640 V
15. Lorraine Halgas, Waltham, Massachusetts, Claims Court Number 90–3641 V
16. David and Diana Martin on behalf of Kyle Martin, Oklahoma City, Oklahoma, Claims Court Number 90–3643 V
17. Carol Burley on behalf of Michael Burley, Barberton, Ohio, Claims Court Number 90–3644 V
18. Carol Burley on behalf of Matthew Burley, Barberton, Ohio, Claims Court Number 90–3645 V
19. Elizabeth Senn on behalf of Mandy Senn, Portland, Oregon, Claims Court Number 90–3646 V
20. Raphael and Renee Adam on behalf of Romanos Anooya, Deceased, Chicago, Illinois, Claims Court Number 90–3647 V
21. Emma Mitchell on behalf of Edward Lee Mitchell, Austin, Texas, Claims Court Number 90–3648 V
22. Andrea Topelian on behalf of Brian Condon, Allen Park, Michigan, Claims Court Number 90–3649 V
23. Theresa MacCloskey on behalf of Kerry MacCloskey, Aurora, Colorado, Claims Court Number 90–3650 V
24. Willie Iyamu on behalf of Osazee Iyamu, Boston, Massachusetts, Claims Court Number 90–3651 V
25. Elizabeth Messer on behalf of Joshua Messer, Riverside, California, Claims Court Number 90–3652 V
26. Elizabeth Messer on behalf of Jared Messer, Riverside, California, Claims Court Number 90–3653 V
27. Michael MacNabb on behalf of Kelly MacNabb, Minneapolis, Minnesota, Claims Court Number 90–3654 V
28. Debra Pugh on behalf of Clayton Pugh, Deceased, Phoenix, Arizona, Claims Court Numbeer 90–3655
29. Barbara Crotty on behalf of Deborah Crotty, Orchard Park, New York, Claims Court Number 90–3656 V
30. Debra Evans on behalf of Christopher Evans, Deceased, Sioux City, Iowa, Claims Court Number 90–3657 V
31. Linda Louthian on behalf of Anthony Louthian, Hudson, Florida, Claims Court Number 90–3658 V
32. Mary Carter on behalf of Steven Carter, Alderson, West Virginia, Claims Court Number 90–3659 V
33. Nancy Rhyne, Weir, Mississippi, Claims Court Number 90–3660 V
34. Brenda Peloso on behalf of Robert Henry, Deceased, Cairo, Georgia, Claims Court Number 90–3661 V
35. Adele Bonvie on behalf of Michael Bonvie, Plainville, Massachusetts, Claims Court Number 90–3662 V
37. Dennis Gunter on behalf of Ashley and Justin Gunter, Fort Smith, Arkansas, Claims Court Number 90–3663 V
38. Yvette Ferguson on behalf of Milton Smith, Jr., Cleveland, Ohio, Claims Court Number 90–3665 V
39. Charles Troop on behalf of Charlotte Troop, Deceased, Boise, Idaho, Claims Court Number 90–3666 V
40. Robert Tichy on behalf of Jonathan Tichy, Louisville, Kentucky, Claims Court Number 90–3667 V
41. Donald Townsend on behalf of Jessica Townsend, Flint, Michigan, Claims Court Number 90–3668 V
42. Gary Wilson, Itasca, Texas, Claims Court Number 90–3669 V
43. Raul Ramirez on behalf of Raul Ramirez, Jr., New Orleans, Louisiana, Claims Court Number 90–3670 V
44. Kenneth Rhea, Spearman, Texas, Claims Court Number 90–3671 V
45. Russell Rhodes on behalf of Lisa Rhodes, Elizabeth, Indiana, Claims Court Number 90–3672 V

46. Ceilia Bumanglag on behalf of Amy Bumanglag, Palmer, Alaska, Claims Court Number 90–3673 V
47. Katherine Burns and Steven Pfeiffer on behalf of Stephanie Pfeiffer, Philadelphia, Pennsylvania, Claims Court Number 90–3674 V
48. Kathleen Mozzayanpour on behalf of Shirin Mozzayanpour, Miami, Florida, Claims Court Number 90–3675 V
49. John and Laurene Nelson on behalf of John K. Nelson, Jr., Narragansett, Rhode Island, Claims Court Number 90–3676 V
50. Maureen Schaeffer on behalf of Nora Schaeffer, Batavia, New York, Claims Court Number 90–3677 V
51. Joseph Lewis on behalf of Kelly Lewis, Williamsville, New York, Claims Court Number 90–3678 V
52. Michael Bapst on behalf of Melissa Bapst, Buffalo, New York, Claims Court Number 90–3679 V
53. Carla Stafford on behalf of Jonathan Stafford, Sandy Hook, Mississippi, Claims Court Number 90–3680 V
54. Steven and Linda Morey on behalf of Timothy Morey, Erie, Pennsylvania, Claims Court Number 90–3681 V
55. John Sykes, Houston, Texas, Claims Court Number 90–3682 V
56. Margaret McFarland on behalf of Jeffrey McFarland, Minden, Louisiana, Claims Court Number 90–3683 V
57. Helena Wray on behalf of Clinton Wray, Goleta, California, Claims Court Number 90–3684 V
58. James Young on behalf of Amber Young, Baldwinsville, New York, Claims Court Number 90–3685 V
59. Mickey Weiser on behalf of Brock Weiser, Hoxie, Kansas, Claims Court Number 90–3686 V
60. Judy Sabri on behalf of Hesham Sabri, Cairo, Egypt, Claims Court Number 90–3687 V
61. Daniel and Jennifer McNally on behalf of Will McNally, Indianapolis, Indiana, Claims Court Number 90–3688 V
62. Michael Walker on behalf of Randy Walker, Odessa, Texas, Claims Court Number 90–3689 V
63. Dorothy Turney on behalf of William Turney, Jr., Edwardsville, Illinois, Claims Court Number 90–3690 V
64. Richard Hammaker on behalf of Adam Hammaker, Miami, Florida, Claims Court Number 90–3691 V
65. Gwendolyn Lewis on behalf of Carla Holmes, Albany, New York, Claims Court Number 90–3692 V
66. Christopher Evans on behalf of Frank Evans, Essex Junction, Vermont, Claims Court Number 90–3693 V
67. Richard and Judith Gleason on behalf of Sharon Gleason, Levittown, New York, Claims Court Number 90–3694 V
68. Sally Lavoie on behalf of O'Neil Lavoie, Lewiston, Maine, Claims Court Number 90–3695 V
69. Dan Goodwin on behalf of Hillary Goodwin, Deceased, Corpus Christi, Texas, Claims Court Number 90–3696 V
70. Jennifer Keith on behalf of Pamela Keith, Jackson, Mississippi, Claims Court Number 90–3697 V
71. Deloris Prewitt on behalf of Tanya Prewitt, Denver, Colorado, Claims Court Number 90–3698 V
72. Ron Kiersey on behalf of Bret Kiersey, Modesto, California, Claims Court Number 90–3699 V
73. Deborah Holzhey, Santa Rosa, California, Claims Court Number 90–3700 V
74. Cheryl Xystros, Sibley, Illinois, Claims Court Number 90–3701 V
75. Robert Cervenka on behalf of Christopher Cervenka, Chicago, Illinois, Claims Court Number 90–3702 V
76. Donald Bastian, Middleburg, Ohio, Claims Court Number 90–3703 V
77. Ralph Becker on behalf of Wesley Becker, Fort Smith, Arkansas, Claims Court Number 90–3704 V
78. Harold Berger on behalf of Sara Berger, Brooklyn, New York, Claims Court Number 90–3705 V
79. Alicia Clover, Trufant, Michigan, Claims Court Number 90–3706 V
80. Susan Collins on behalf of Betsy Collins, Dallas, Texas, Claims Court Number 90–3707 V
81. Myron Carterman on behalf of Diana Carterman, Kent, Washington, Claims Court Number 90–3708 V
82. Barbara Fuller on behalf of Sara Fuller, Kissimmee, Florida, Claims Court Number 90–3709 V
83. Kaye Caroll, Lampasas, Texas, Claims Court Number 90–3710 V
84. Gregory Caudill, Barberton, Ohio, Claims Court Number 90–3711 V
85. Edward Carrico on behalf of Shane Carrico, Deceased, Nutter Fort Stonewood, West Virginia, Claims Court Number 90–3712 V
86. Gary Cahill on behalf of Donald Cahill, Deceased, Mooresville, Indiana, Claims Court Number 90–3713 V
87. Robert Jackson on behalf of Arnel Jackson, Houston, Texas, Claims Court Number 90–3714 V
88. Marguerite Ward on behalf of Christopher Jones, Merrillville, Indiana, Claims Court Number 90–3715 V
89. Kelley Jackson on behalf of Arthur Jackson, Brownwood, Texas, Claims Court Number 90–3716 V
90. Joseph Jenkins on behalf of Charles Jenkins, Jacksonville, North Carolina, Claims Court Number 90–3717 V
91. Tommie Jordon on behalf of Alton Jordon, Metairie, Louisiana, Claims Court Number 90–3718 V
92. Blake Breedveld on behalf of Christopher Medina, Chicago, Illinois, Claims Court Number 90–3719 V
93. Eric Bergerson, Silver Spring, Maryland, Claims Court Number 90–3720 V
94. Carolyn Barnes on behalf of Nicholas Barnes, Soldotna, Alaska, Claims Court Number 90–3721 V
95. Michael Alder, Watseka, Illinois, Claims Court Number 90–3722 V
96. Vanessa Anthony on behalf of Jarreau Anthony, Ft. Riley, Kansas, Claims Court Number 90–3723 V
97. Betty Alexander on behalf of Janet Alexander, Meridian, Mississippi, Claims Court Number 90–3724 V
98. Charles Pedersen on behalf of John Pedersen, Portland, Oregon, Claims Court Number 90–3725 V
99. Rick Middleton on behalf of Clinton Middleton, Springfield, Oregon, Claims Court Number 90–3726 V
100. Norman Van Leuven on behalf of Jennifer Van Leuven, Deceased, Prineville, Oregon, Claims Court Number 90–3727 V
101. David and Cindy Smith on behalf of Stephanie Smith, Deceased, Portland, Oregon, Claims Court Number 90–3728 V
102. John Doyle on behalf of Mary Doyle, Bronx, New York, Claims Court Number 90–3729 V
103. Tamara Hampton on behalf of Robbie Lee Hampton, Patrick AFB, Florida, Claims Court Number 90–3730 V
104. Evelyn Holmes on behalf of Susan Rawlings, Philadelphia, Pennsylvania, Claims Court Number 90–3731 V
105. Susan Kelly, Saginaw, Michigan, Claims Court Number 90–3732 V
106. Billy Henson, Jr., Weir, Mississippi, Claims Court Number 90–3733 V
107. Carol McLeod on behalf of Darin McLeod, Portland, Oregon, Claims Court Number 90–3734 V
108. Christopher Zwart, Dell Rapids, South Dakota, Claims Court Number 90–3735 V
109. Belinda Sons on behalf of Jared Sons, Salem, Indiana, Claims Court Number 90–3736
110. Sandra Erb on behalf of Kerry Erb, Honeoye Falls, New York, Claims Court Number 90–3737 V
111. Ronald Venard on behalf of Tyson Venard, Longview, Washington, Claims Court Number 90–3738 V
112. Naomi Kasten on behalf of Shira Kasten, Oceanside, New York, Claims Court Number 90–3739 V

113. Dianna Anderson on behalf of Erika Anderson, Deceased, Moline, Illinois, Claims Court Number 90–3741 V
114. Donna Anderson on behalf of Darla Anderson, Watertown, South Dakota, Claims Court Number 90–3742 V
115. Lynne Schone on behalf of Amanda Schone, Biloxi, Mississippi, Claims Court Number 90–3743 V
116. Thomas J. Delaune on behalf of Thomas R. Delaune, Metairie, Louisiana, Claims Court Number 90–3744 V
117. Christopher Frontera, Detroit, Michigan, Claims Court Number 90–3745 V
118. Fred Fulton on behalf of Laura Fulton, Dallas, Texas, Claims Court Number 90–3746 V
119. Lenna Dee Kyle, Red Bluff, California, Claims Court Number 90–3747 V
120. Coche and Evelyn Gilbert on behalf of Peter Gilbert, Cleveland, Mississippi, Claims Court Number 90–3748 V
121. Coche Gilbert, Hattiesburg, Mississippi, Claims Court Number 90–3749 V
122. Fredrick Kamienny on behalf of Howard Kamienny, Deceased, Southfield, Michigan, Claims Court Number 90–3750 V
123. Beth Turpin on behalf of Andrew Turpin, Deceased, Greenfield, Indiana, Claims Court Number 90–3751 V
124. Carol Freeman, Richland, Washington, Claims Court Number 90–3752 V
125. Thomas Graham on behalf of Wesley Graham, St. Louis, Missouri, Claims Court Number 90–3753 V
126. Enedelia Mendez on behalf of Santos Mendez, Crescent City, Florida, Claims Court Number 90–3754 V
127. Lucille Tabor on behalf of Joel Tabor, Deceased, Princeton, West Virginia, Claims Court Number 90–3755 V
128. Ruben Lapitan on behalf of Melanie Lapitan, Honolulu, Hawaii, Claims Court Number 90–3756 V
129. Norris Jenkins on behalf of Burwell Jenkins, Deceased, Philadelphia, Pennsylvania, Claims Court Number 90–3757 V
130. Heidi Starr on behalf of Jessica Sterling, Canoga Park, California, Claims Court Numbers 90–3758 V
131. Diane VanDusen, Gibsonton, Florida, Claims Court Number 90–3759 V
132. Benjamin Allgyer on behalf of J. Michael Allgyer, Gordonville, Pennsylvania, Claims Court Number 90–3760 V
133. Bernice Ditchfield on behalf of Laureign Ditchfield, Deceased, Portsmouth, Virginia, Claims Court Number 90–3761 V
134. Paul Ritzer, Walpole, Massachusetts, Claims Court Number 90–3762 V
135. Wanda Justice on behalf of Sunny Justice, Las Vegas, Nevada, Claims Court Number 90–3763 V
136. David Silvius, Yarmouth, Maine, Claims Court Number 90–3764 V
137. Linda Roth on behalf of David Roth, Mount Lebanon, Pennsylvania, Claims Court Number 90–3765 V
138. Jeffrey Moore on behalf of June Moore, Deceased, Midwest City, Oklahoma, Claims Court Number 90–3766 V
139. Walter Lynch on behalf of Jeffrey Lynch, Wayland, Michigan, Claims Court Number 90–3767 V
140. Gary and Sharon Neese on behalf of Crista Neese, Brazil, Indiana, Claims Court Number 90–3768 V
141. Jana Donald on behalf of Aubrey Donald, Waynesboro, Mississippi, Claims Court Number 90–3769 V
142. Manuel Alvarez on behalf of Manuel Vergne, Santurce, Puerto Rico, Claims Court Number 90–3770 V
143. Ryan Burns, Gardner, Massachusetts, Claims Court Number 90–3771 V
144. Christine Nesmith, Lincoln, Nebraska, Claims Court Number 90–3772 V
145. Corey Kirk on behalf of Charles Hulsey, Oklahoma City, Oklahoma, Claims Court Number 90–3774 V
146. Michael Collins, Detroit, Michigan, Claims Court Number 90–3775 V
147. Roy Howard, Jr., Oklahoma City, Oklahoma, Claims Court Number 90–3776 V
148. David Perret on behalf of Cynthia Perret, Deceased, New Orleans, Louisiana, Claims Court Number 90–3777 V
149. Bobby Joe Atkins, Rockmart, Georgia, Claims Court Number 90–3778 V
150. John Nicholson, New Orleans, Louisiana, Claims Court Number 90–3779 V
151. Ruby Hulet on behalf of Jon C. Hulet, Anoka, Minnesota, Claims Court Number 90–3780 V
152. Thomas Hull on behalf of Alison Hull, Wiesbaden, West Germany, Claims Court Number 90–3781 V
153. Joy McKenzie on behalf of Marlaina Lewin, New York, New York, Claims Court Number 90–3782 V
154. Julia Lamb on behalf of Seth Lamb, Fawn Grove, Pennsylvania, Claims Court Number 90–3783 V
155. LaWanda Scroggins, San Francisco, California, Claims Court Number 90–3784 V
156. Billy Hampton, Bland, Virginia, Claims Court Number 90–3785 V
157. Jeanette Woods on behalf of Lance Woods, Miami Beach, Florida, Claims Court Number 90–3786 V
158. Mary Golden on behalf of Inga Nickel, Sacramento, California, Claims Court Number 90–3787 V
159. David Trevino on behalf of Catherine Trevino, Robstown, Texas, Claims Court Number 90–3788 V
160. Betty Barrett on behalf of Tom Barrett, Augusta, Georgia, Claims Court Number 90–3790 V
161. Teresa Watson, Mc Rae, Georgia, Claims Court Number 90–3791 V
162. Terrence Benton on behalf of Brandon Benton, Staunton, Virginia, Claims Court Number 90–3792 V
163. Larry and Janette Pepper, Jr., on behalf of Amy Gibbs, Wheeling, West Virginia, Claims Court Number 90–3793 V
164. E.J. Hickman on behalf of Mary Hickman, Scott A F B, Illinois, Claims Court Number 90–3794 V
165. Linda LaRue on behalf of Daniel LaRue, Milwaukee, Wisconsin, Claims Court Number 90–3795 V
166. Sandra Jean Pollins, Charleston, South Carolina, Claims Court Number 90–3796 V
167. Edward Hart on behalf of Brian Hart, Reynoldsburg, Ohio, Claims Court Number 90–3797 V
168. Joseph McCoy on behalf of Ramon Villegas, San Benito, Texas, Claims Court Number 90–3798 V
169. Geraldine Correia on behalf of Cherie Correia, Daytona Beach, Florida, Claims Court Number 90–3799 V
170. Delores Williams on behalf of Teri Konchalski, San Francisco, California, Claims Court Number 90–3800 V
171. Tina Gomez on behalf of Veronica Gomez, Deceased, Pittsburg, California, Claims Court Number 90–3801 V
172. Catherine Dunning on behalf of Megan Dunning, Chino, California, Claims Court Number 90–3802 V
173. Steve Brunson, Gadsden, Alabama, Claims Court Number 90–3803 V
174. Roger Clay on behalf of Courtney Clay, Minneapolis, Minnesota, Claims Court Number 90–3804 V
175. Eleanor Diaz on behalf of Crystal Diaz, Tucson, Arizona, Claims Court Number 90–3805 V
176. Louise Harpley, Augusta, Georgia, Claims Court Number 90–3806 V
177. Benny Kelly on behalf of Erin Kelly, Dodge City, Kansas, Claims Court Number 90–3807 V
178. Annie Hobson on behalf of Calvin Hobson, Memphis, Tennessee, Claims Court Number 90–3808 V

179. Mylyndia Duncan, Drexel Hill, Pennsylvania, Claims Court Number 90–3809 V
180. Robert Whitley on behalf of Mark Whitley, Rogers, Arkansas, Claims Court Number 90–3810 V
181. Barbara Miller, Auburn, New York, Claims Court Number 90–3811 V
182. Diana Stark on behalf of Corey Stark, Deceased, Brattleboro, Vermont, Claims Court Number 90–3812 V
183. Marie Skrzypchak on behalf of Pamela Skrzypchak, Wausau, Wisconsin, Claims Court Number 90–3813 V
184. Gale Stanford, Birmingham, Alabama, Claims Court Number 90–3815 V
185. Monte Hancock, Salt Lake City, Utah, Claims Court Number 90–3817 V
186. Karen Harmon, Butler, Pennsylvania, Claims Court Number 90–3818 V
187. Virginia Mercer on behalf of Edwin Cusick Maeurer, Jersey City, New Jersey, Claims Court Number 90–3819 V
188. Leslie Martin on behalf of Peter Martin, New Orleans, Louisiana, Claims Court Number 90–3820 V
189. Woodrow Gerdon on behalf of Monroe Gerdon, Deceased, Corydon, Indiana, Claims Court Number 90–3821 V
190. Charles Rath, Chicago, Illinois, Claims Court Number 90–3822 V
191. James Cline on behalf of Jonathan Cline, Appleton, Wisconsin, Claims Court Number 90–3823 V
192. Michael Dewey on behalf of Jeremy Dewey, Deceased, San Jose, California, Claims Court Number 90–3824 V
193. Zoe Backman on behalf of Janyne Holtzman, Bellmore, New York, Claims Court Number 90–3825 V.

Dated: November 17, 1993.

William A. Robinson,

Acting Administrator

[FR Doc. 93–28669 Filed 11–22–93; 8:45 am]

BILLING CODE 4160–15–P

INTERNATIONAL TRADE COMMISSION

[Investigations Nos. 731–TA–671–674 (Preliminary)]

Silicomanganese From Brazil, the People's Republic of China, Ukraine, and Venezuela

AGENCY: United States International Trade Commission.

ACTION: Institution and scheduling of preliminary antidumping investigations.

SUMMARY: The Commission hereby gives notice of the institution of preliminary antidumping investigations Nos. 731–TA–671–674 (Preliminary) under section 733(a) of the Tariff Act of 1930 (19 U.S.C. 1673b(a)) to determine whether there is a reasonable indication that an industry in the United States is materially injured, or is threatened with material injury, or the establishment of an industry in the United States is materially retarded, by reason of imports from Brazil, the People's Republic of China, Ukraine, and Venezuela of silicomanganese (ferrosilicon manganese), provided for in subheading 7202.30.00 of the Harmonized Tariff Schedule of the United States, that are alleged to be sold in the United States at less than fair value. The Commission must complete preliminary antidumping investigations in 45 days, or in this case by December 27, 1993.

For further information concerning the conduct of these investigations and rules of general application, consult the Commission's Rules of Practice and Procedure, part 201, subparts A through E (19 CFR part 201), and part 207, subparts A and B (19 CFR part 207).

EFFECTIVE DATE: November 12, 1993.

FOR FURTHER INFORMATION CONTACT: Janine Wedel (202–205–3178), Office of Investigations, U.S. International Trade Commission, 500 E Street SW., Washington, DC 20436. Hearing-impaired persons can obtain information on this matter by contacting the Commission's TDD terminal on 202–205–1810. Persons with mobility impairments who will need special assistance in gaining access to the Commission should contact the Office of the Secretary at 202–205–2000.

SUPPLEMENTARY INFORMATION:

Background

These investigations are being instituted in response to a petition filed on November 9, 1993, by Elkem Metals Company, Pittsburgh, PA, and the Oil, Chemical and Atomic Workers, Local, Belpre, OH.

Participation in the investigations and public service list.

Persons (other than petitioners) wishing to participate in the investigations as parties must file an entry of appearance with the Secretary to the Commission, as provided in sections 201.11 and 207.10 of the Commission's rules, not later than seven (7) days after publication of this notice in the **Federal Register**. The Secretary will prepare a public service list containing the names and addresses of all persons, or their representatives, who are parties to these investigations upon the expiration of the period for filing entries of appearance.

Limited Disclosure of Business Proprietary Information (BPI) Under an Administrative Protective Order (APO) and BPI Service List

Pursuant to section 207.7(a) of the Commission's rules, the Secretary will make BPI gathered in these preliminary investigations available to authorized applicants under the APO issued in the investigations, provided that the application is made not later than seven (7) days after the publication of this notice in the **Federal Register**. A separate service list will be maintained by the Secretary for those parties authorized to receive BPI under the APO.

Conference

The Commission's Director of Operations has scheduled a conference in connection with these investigations for 9:30 a.m. on December 3, 1993, at the U.S. International Trade Commission Building, 500 E Street SW., Washington, DC. Parties wishing to participate in the conference should contact Janine Wedel (202–205–3178) not later than November 30, 1993, to arrange for their appearance. Parties in support of the imposition of antidumping duties in these investigations and parties in opposition to the imposition of such duties will each be collectively allocated one hour within which to make an oral presentation at the conference. A nonparty who has testimony that may aid the Commission's deliberations may request permission to present a short statement at the conference.

Written Submissions

As provided in sections 201.8 and 207.15 of the Commission's rules, any person may submit to the Commission on or before December 8, 1993, a written brief containing information and arguments pertinent to the subject matter of the investigations. Parties may file written testimony in connection with their presentation at the conference no later than three (3) days before the conference. If briefs or written testimony contain BPI, they must conform with the requirements of sections 201.6, 207.3, and 207.7 of the Commission's rules.

In accordance with sections 201.16(c) and 207.3 of the rules, each document filed by a party to the investigations must be served on all other parties to the investigations (as identified by either the public or BPI service list), and

a certificate of service must be timely filed. The Secretary will not accept a document for filing without a certificate of service.

Authority: These investigations are being conducted under authority of the Tariff Act of 1930, title VII. This notice is published pursuant to section 207.12 of the Commission's rules.

Issued: November 18, 1993.

By order of the Commission.

Donna R. Koehnke,

Secretary.

[FR Doc. 93–28754 Filed 11–22–93; 8:45 am]

BILLING CODE 7020–02–M

INTERSTATE COMMERCE COMMISSION

[Ex Parte No. 290 (Sub-No. 2)]

Railroad Cost Recovery Procedures

AGENCY: Interstate Commerce Commission.

ACTION: Final decision.

SUMMARY: The Commission declines to change the methodology for weighting the index used to calculate the quarterly rail cost adjustment factor. The weighting methodology currently in use will be continued.

EFFECTIVE DATE: December 22, 1993.

FOR FURTHER INFORMATION CONTACT: Thomas A. Schmitz, (202) 927-5720, or Robert C. Hasek, (202) 927-6239. [TDD for hearing impaired: (202) 927-5721.]

SUPPLEMENTARY INFORMATION: The RCAF is a quarterly index that measures changes in railroad expenses. It is composed of various components that are weighted together and revised annually to insure proportional representation of each component in the RCAF index. The Association of American Railroads petitioned for a proposed change in the weighting methodology to accommodate special charges related to labor buyouts and depreciation charges. A coalition of shippers proposed an alternative methodology. The Commission concluded that the methodology currently in use is superior to any of the suggested proposals.

Additional information is contained in the Commission's decision. To purchase a copy of the full decision write to, or call, or pick up in person from: Dynamic Concepts, Inc., Room 2229, Interstate Commerce Commission Building, Washington, DC 20423, or telephone (202) 289-4357/4359. [Assistance for the hearing impaired is available through TDD service (202) 927-5721.]

Decided: November 12, 1993.

By the Commission, Chairman McDonald, Vice Chairman Simmons, Commissioners Phillips, Philbin and Walden.

Sidney L. Strickland, Jr.,

Secretary.

[FR Doc. 93–28725 Filed 11–22–93; 8:45 am]

BILLING CODE 7035–01–P

[Docket No. AB–399X]

Golden Cat Railroad Corporation—Abandonment Exemption—In Scott and Cape Girardeau Counties, MO

AGENCY: Interstate Commerce Commission.

ACTION: Notice of exemption.

SUMMARY: The Commission exempts from the prior approval requirements of 49 U.S.C. 10903–04 The abandonment by The Golden Cat Railroad Corporation, of 10.3-miles of rail line extending between milepost 150.0, at or near Delta, and the end of The line at milepost 160.3, at or near Newman Spur, in Scott and Cape Girardeau Counties, MO.

DATES: The exemption will be effective on December 8, 1993, unless a formal expression of intent to file an offer of financial assistance is filed. Formal expressions of intent to file an offer of financial assistance under 49 CFR 1152.27(c)(2)[1] must be filed by December 3, 1993; petitions to stay must be filed by December 3 1993; requests for a public use condition must be filed by December 3, 1993; and petitions to reopen must be filed by December 13, 1993.

ADDRESSES: Send pleadings referring to Docket No. AB–399X to: (1) Office of the Secretary, Case Control Branch, Interstate Commerce Commission, Washington, DC 20423; and (2) Petitioner's representative: Robert B. Hebert, 1800 INB Tower, One Indiana Square, Indianapolis, IN 46204.

FOR FURTHER INFORMATION CONTACT: Richard B. Felder, (202) 927–5610. [TDD for hearing impaired: (202) 927–5721.]

SUPPLEMENTARY INFORMATION: Additional information is contained in the Commission's decision. To purchase a copy of the full decision, write to, call, or pick up in person from: Dynamic Concepts, Inc., room 2229, Interstate Commerce Commission Building, Washington, DC 20423. Telephone: (202) 289–4357/4359. [Assistance for the hearing impaired is available through TDD services (202) 927–5721.]

Decided: November 17, 1993.

[1] *See Exempt. of Rail Abandonment—Offers of Finan. Assist.*, 4 I.C.C.2d 164 (1987).

By The Commission, Chairman McDonald, Vice Chairman Simmons, Commissioners Phillips, Philbin, and Walden.

Sidney L. Strickland, Jr.,

Secretary.

[FR Doc. 93–28872 Filed 11–22–93; 8:45 am]

BILLING CODE 7035–01–P

[Finance Docket No. 32389]

LWR, Inc.—Acquisition and Operation Exemption—Lines of Consolidated Rail Corp.

LWR, Inc. (LWR), a noncarrier, has filed a notice of exemption to acquire from Consolidated Rail Corporation (Conrail) 5.5 miles of the following lines of railroad in Carroll, Stark, and Columbiana Counties, OH: (1) The Tuscarawas Industrial Track–LC 40–2427, from milepost O.O at point of connection to the Bayard siding in Bayard, to milepost 2.9 at the end of Conrail ownership, 175 feet west of Grant Street in Minerva, including the Conrail operating easement between mileposts 2.7 and 2.9; (2) the Piney Fork Industrial Track–LC 40–2446, from milepost 40.9 at the beginning of Conrail's ownership in Minerva, to milepost 43.5 at the end of Conrail's ownership in Minerva, including all track, facilities, and property comprising Minerva Yard; and (3) the "Horn Track," a short connecting track between the Tuscarawas Industrial Track and the Piney Fork Industrial Track, between Grant Street and Sandy Creek Bridge. LWR will enter into an agreement with Ohi-Rail Corp. to operate the line in a contract carrier capacity and not as a rail common carrier. The parties intended to consummate the transaction on or after October 31, 1993.[1]

Any comments must be filed with the Commission and served on: Richard R. Wilson, 2310 Grant Building, Pittsburgh, PA 15219.

This notice is filed under 49 CFR 1150.31. If the notice contains any false or misleading information, the exemption is void *ab initio*. Petitions to revoke the exemption under 49 U.S.C. 10505(d) may be filed at any time. The filing of a petition to revoke will not automatically stay the transaction.

Decided: November 15, 1993.

[1] Under 49 CFR 1150.32(b), exemptions become effective 7 days after the exemption notice is filed. In this case, the notice of exemption was not filed until October 29, 1993, and thus the exemption was not effective until November 5, 1993. Petitioner's representative has confirmed that the correct consummation date is on or after November 5, 1993.

By the Commission, David M. Konschnik, Director, Office of Proceedings.

Sidney L. Strickland, Jr.

Secretary.

[FR Doc. 93-28726 Filed 11-22-93; 8:45 am]

BILLING CODE 7035-01-P

[Docket No. AB-401X]

Oregon Pacific & Eastern Railway Co.—Abandonment Exemption—Lane County, OR

Oregon Pacific & Eastern Railway Company (OP&E) has filed a notice of exemption under 49 CFR Part 1152, Subpart F—Exempt Abandonments to abandon its 14.15-mile line of railroad from milepost 3.35 near Mosby Creek, to milepost 17.5 near Culp Creek, in Lane County, OR.[1]

OP&E has certified that: (1) No local traffic has moved over the line for at least 2 years; (2) there is no overhead traffic on the line; and (3) no formal complaint filed by a user of rail service on the line (or by a State or local government entity acting on behalf of such user) regarding cessation of service over the line either is pending with the Commission or with any U.S. District Court or has been decided in favor of the complainant within the 2-year period; and (4) the requirement at 49 CFR 1152.50(d)(1) (notice to government agencies) has been met.

As a condition to use of this exemption, any employee affected by the abandonment shall be protected under Oregon Short Line R. Co.—Abandonment—Goshen, 360 I.C.C. 91 (1979). To address whether this condition adequately protects affected employees, a petition for partial revocation under 49 U.S.C. 10505(d) must be filed.

Provided no formal expressions of intent to file an offer of financial assistance (OFA) has been received, this exemption will be effective on December 23, 1993, unless stayed pending reconsideration. Petitions to stay that do not involve environmental issues,[2] formal expressions of intent to file an OFA under 49 CFR 1152.27(c)(2),[3] and trail use/rail banking statements under 49 CFR 1152.29[4] must be filed by December 3, 1993. Petitions to reopen or requests for public use conditions under 49 CFR 1152.28 must be filed by December 13, 1993, with: Office of the Secretary, Case Control Branch, Interstate Commerce Commission, Washington, DC 20423.

A copy of any pleading filed with the Commission should be sent to applicant's representative: Douglas M. Ragen, 111 SW. Fifth Avenue, Portland, OR 97204.

If the notice of exemption contains false or misleading information, the exemption is void *ab initio*.

Applicant has filed an environmental report which addresses the abandonment's effect, if any, on the environmental or historic resources. The Section of Energy and Environment (SEE) will issue an environmental assessment (EA) by November 26, 1993. Interested persons may obtain a copy of the EA from SEE by writing to it (room 3219, Interstate Commerce Commission, Washington, DC 20423) or by calling Elaine Kaiser, Chief of SEE, at (202) 927-6248. Comments on environmental and historic preservation matters must be filed within 15 days after the EA becomes available to the public.

Environmental, historic preservation, public use, or trail use/rail banking conditions will be imposed, where appropriate, in a subsequent decision.

Decided: November 12, 1993.

By the Commission, David M. Konschnik, Director, Office of Proceedings.

Sidney L. Strickland, Jr.,

Secretary.

[FR Doc. 93-28727 Filed 11-22-93; 8:45 am]

BILLING CODE 7035-01-P

[Finance Docket No. 32264]

Public Service Co. of Colorado—Acquisition Exemption—Line of the Colorado and Wyoming Railway Co.

Public Service Company of Colorado (PSC), a noncarrier, seeks to acquire a 4.5 mile rail line, known as the Comanche Spur[1], located in Pueblo County, CO from The Colorado and Wyoming Railway Company (Old C&W).[2] The parties expected consummation to occur on March 4, 1993.

Any comments must be filed with the Commission and served on George P. Green, Manager, Electric Supply Resources, Public Service Company of Colorado, 1225 17th Street, Denver, CO 80202.

This transaction is related to the restructuring of CF&I Steel Corporation[3] pursuant to a plan of reorganization approved by the bankruptcy court.[4] PSC is acquiring the Comanche Spur from Colorado and Utah Land Company and CF&I Steel Corporation by designation of CF&I Steel L.P and from Old C&W. The operations on the line will be conducted by New C&W pursuant to a service agreement with PSC.[5] As a condition to the use of this exemption, any employee adversely affected by the transaction will be protected by the conditions set forth in New York Dock Ry.—Control—Brooklyn Eastern Dist., 360 I.C.C. 60 (1979).[6]

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[1] Pursuant to 49 CFR 1152.50(d)(2), the railroad must file a verified notice with the Commission at least 50 days before the abandonment or discontinuance is to be consummated. The applicant, in its verified notice, indicated a proposed consummation date of December 20, 1993. Because the verified notice was not filed until November 3, 1993, consummation should not have been proposed to take place prior to December 23, 1993. Applicant's representative has confirmed that the correct consummation date is on or after December 23, 1993.

[2] A stay will be routinely issued by the Commission in those proceedings where an informed decision on environmental issues (whether raised by a party or by the Commission's Section of Energy and Environment in its independent investigation) cannot be made prior to the effective date of the notice of exemption. See Exemption of Out-of-Service Rail Lines, 5 I.C.C.2d 377 (1989). Any entity seeking a stay involving environmental concerns is encouraged to file its request as soon as possible in order to permit this Commission to review and act on the request before the effective date of this exemption.

[3] See Exempt. of Rail Abandonment—Offers of Finan. Assist., 4 I.C.C.2d 164 (1987).

[4] The Commission will accept a late-filed trail use statement as long as it retains jurisdiction to do so.

[1] In spite of its name, the line does not appear to be a spur within the meaning of 49 U.S.C. 10907.

[2] In a notice of exemption served March 22, 1993 in Finance Docket No. 32263, the Commission exempted Colorado and Wyoming Railway Company's (New C&W),: (1) Acquisition and operation of approximately 1 mile of rail line, including associated feeder lines, owned by The Colorado and Wyoming Railway Company (Old C&W) located within the boundaries of the CF&I steel mill property in Pueblo, Co; and (2) operations over the Comanche Spur, which PSC seeks to acquire here. That transaction was subject to labor protective conditions.

[3] On November 7, 1990, CF&I Steel Corporation (Old CF&I) and its subsidiaries, including Old C&W, filed for reorganization under Chapter 11 of the Bankruptcy Code. Prior to reorganization, Oregon Steel Mills, Inc. controlled Old CF&I, which in turn controlled Old C&W. Pursuant to a plan of reorganization approved by the Bankruptcy Court in *In Re CF&I Fabricator of Utah, Inc.*, No. 90b-6721, (D. Utah Dec. 1, 1992) a limited partnership, consisting of New CF&I, Inc. (the general partner) and the Pension Benefit Guaranty Corporation (the limited partner), purchased certain assets of Old CF&I and all of the remaining assets of Old C&W. The New C&W will be a wholly owned subsidiary of New CF&I, which in turn will be a wholly owned subsidiary of Oregon Steel Mills, Inc. Also in that proceeding the Bankruptcy Court authorized the sale of the Comanche Spur to PSC.

[4] Pursuant to 49 CFR part 1180 Subpart B, transactions under 11 U.S.C. 1172 involving the transfer or operation of lines of bankrupt railroads, by a noncarrier, under a plan of reorganization are governed by the procedures in 49 CFR 1150, subpart D. See Transfer of Operation of Lines of Railroads in Reorganization, 9 I.C.C.2d 201 (1992) (Reorganization).

[5] PSC also filed a motion to dismiss this proceeding for lack of jurisdiction. That motion has been denied in a Commission decision in Finance Docket No. 32264 (not printed), served November 10, 1993.

[6] In these types of transactions, pursuant to 49 CFR part 1180, subpart B, the Commission is

Continued

This notice is filed under 49 CFR 1180.20 and 1150.31. If the notice contains false or misleading information, the exemption is void *ab initio*. Petitions to revoke the exemption under 49 U.S.C. 10505(d) may be filed at any time. The filing of a petition to revoke will not automatically stay the transaction.

Decided: November 16, 1993.

By the Commission, David M. Konschnik, Director, Office of Proceedings.

Sidney L. Strickland, Jr.

Secretary.

[FR Doc. 93–28728 Filed 11–22–93; 8:45 am]

BILLING CODE 7035–01–P

DEPARTMENT OF LABOR

Bureau of Labor Statistics

Business Research Advisory Council; Meeting and Agenda

The regular Fall meeting of the Committee on Occupational Safety and Health of the Business Research Advisory Council will be held on December 16, 1993, at 1 p.m. The meeting will be held in Meeting Room 4 of the Postal Square Building Conference Center, 2 Massachusetts Avenue, NE., Washington, DC.

The Business Research Advisory Board and its committees advise the Bureau of Labor Statistics with respect to technical matters associated with the Bureau's programs from American business and industry.

The schedule and agenda for the meeting is as follows:

Thursday, December 16, 1993

1–4 p.m.—Committee on Occupational Safety and Health Statistics

a. 1992 Survey of Occupational Injuries and Illnesses
   a. Lost workday measures
   b. Table formats for worker demographic and case characteristics data
   c. Availability of state data
   d. Department of Labor report on data needs to the House and Senate Appropriations Committees
   e. Title VIII, OSHA Reform Act (proposed)
2. 1992 Census of Fatal Occupational Injuries: availability of state data
3. Other business

The meeting is open to the public. Persons with disabilities wishing to attend should contact Constance B. DiCesare, Liaison, Business Research Advisory Council, at (202) 606–5886, for appropriate accommodations.

Signed at Washington, DC the 15th day of November 1993.

Katherine G. Abraham,

Commissioner.

[FR Doc. 93–28757 Filed 11–22–93; 8:45 am]

BILLING CODE 4510–24–M

Office of Federal Contract Compliance Programs

Layton Construction Company, Inc, Debarment

AGENCY: Office of Federal Contract Compliance Programs, Labor.

ACTION: Notice of Debarment, Layton Construction Company, Inc.

SUMMARY: This notice advises of the debarment of Layton Construction Company, Inc. (hereinafter "Layton"), as an eligible bidder on Government contracts and subcontracts and Federally-assisted construction contracts and subcontracts. The debarment is effective immediately.

FOR FURTHER INFORMATION CONTACT: Leonard J. Biermann, Acting Director, Office of Federal Contract Compliance Programs, U.S. Department of Labor, 200 Constitution Ave., NW., room C–3325, Washington, DC 20210 (202–219–9475).

SUPPLEMENTARY INFORMATION: On November 1, 1993, pursuant to 41 CFR 60–30.13(a), the Deputy Chief Administrative Law Judge issued a Decision and Order approving the Consent Decree entered into by Layton and OFCCP. Under the terms of the Consent Decree, Layton and its officers, agents, servants, employees, successors, divisions and subsidiaries, and those persons in active concert or participation with them, are declared ineligible for the award of any contracts or subcontracts funded in whole or in part with Federal funds and ineligible for extension or other modifications of any existing Government contracts or subcontracts; and federally assisted construction contracts and subcontracts. The Decision and Order is set forth below.

The debarment from future Government contracts and subcontracts and the ineligibility for extensions or other modifications is effective immediately and shall be lifted once Layton has satisfied the Director of OFCCP that it is in compliance with the Consent Decree for ninety days.

Signed November 16, 1993, Washington, DC.

Leonard J. Biermann,

Acting Director, OFCCP.

Date Issued: November 1, 1993.

Case No.: 93–OFC–17.

In the Matter of *Office of Federal Contract Compliance Programs, U.S. Department of Labor*, Plaintiff, v. *Layton Construction Company, Inc.*, Defendant.

Before: John M. Vittone, Deputy Chief Judge.

Decision and Order

This case arises under Executive Order No. 11246, 30 FR 12,319, as amended by Executive Order No. 11375, 32 FR 14,303 and Executive Order No. 12086, 43 FR 46,501; Section 503 of the Rehabilitation Act of 1973, as amended, 29 U.S.C. 793; and Vietnam Era Veterans' Readjustment Assistance Act of 1974, 38 U.S.C. 4212 and the regulations thereunder.

On September 3, 1993, the Office of Federal Contract Compliance Programs of the United States Department of Labor (DOL) filed a Complaint against Layton Construction Company (Defendant) with the Office of Administrative Law Judges. DOL alleges that Defendant violated the terms of the attached Conciliation Agreement entered into on May 10, 1990.

With the Complaint, DOL filed an executed Consent Decree with this Office. DOL and Defendant report that they have resolved all disputed claims. Defendant, without admitting any violations, has agreed to comply with the terms of the Conciliation Agreement and the Consent Decree. Pursuant to 41 CFR 60–30.13(a), the parties request review of the agreement and an order disposing of this proceeding.

Upon review of the record, the Consent Decree is hereby approved. Such agreement constitutes full and final resolution of this matter. It is further ordered that:

(1) this order shall have the same force and effect as an order after full hearing;

(2) the entire record upon which this order is based shall consist solely of the Complaint and this agreement;

(3) any further procedural steps before this Office are waived; and

(4) any right to challenge or contest the validity of this order entered into in

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required under 11 U.S.C. 1172(c)(1) to provide affected employees with adequate protection, as set forth in 49 U.S.C. 11347, unless a need is shown for greater levels of protection. See Reorganization, supra.

The United Transportation Union and Transportation Communications International Union (petitioners), jointly filed on March 24, 1993, a petition to revoke, and an alternative request for imposition of labor protection. PSC filed a response to that petition on April 12, 1993. The petition to revoke has been denied in a Commission decision served in Finance Docket No. 32264 on November 10, 1993. In accordance with 49 CFR 1180.20(c), appropriate labor protective conditions have been imposed providing the alternative relief sought by petitioners.

accordance with this agreement is waived.

In accordance with 41 CFR 60–30.13(d), this Decision and Order shall constitute the final administrative order.

John M. Vittone,

Deputy Chief Judge.

Consent Decree

This Consent Decree is entered into between the Plaintiff, United States Department of Labor, Office of Federal Contract Compliance Programs (hereinafter "OFCCP"), and Defendant Layton Construction Company, Inc. (hereinafter "Defendant") in resolution of the Administrative Compliant filed by OFCCP pursuant to Executive Order 11246 (30 FR 12319), as amended by Executive Order 11375 (32 FR 14303) and Executive Order 12086 (43 FR 46501) ("Executive Order"), Section 503 of the Rehabilitation Act of 1973, as amended, 29 U.S.C. 793 ("Section 503"), and Section 4212 of the Vietnam Era Veterans' Readjustment Assistance Act, 38 U.S.C. 4212. The Administrative Complaint alleged that Defendant violated the terms of a Conciliation Agreement which was executed by Defendant and OFCCP and which became effective on May 10, 1990.

Part A. General Provisions

1. The record on the basis of which this Consent Decree is entered shall consist of the Complaint and the Consent Decree and the attachments thereto.

2. Attachment A of the Consent Decree consists of the Conciliation Agreement between OFCCP and Defendant which became effective on May 10, 1990.

3. This Consent Decree shall not become final until it has been signed by the Administrative Law Judge and the effective date of the Decree shall be the date it is signed by the Administrative Law Judge.

4. This Consent Decree shall be binding upon Defendant and any and all purchasers, successors, assignees, and/or transferees, and shall have the same force and effect as an order made after a full hearing.

5. All further procedural steps to contest the binding effect of the Consent Decree, and any right to challenge or contest the obligations entered into in accordance with the agreement contained in this Decree, are waived by the parties.

6. Subject to the performance by Defendant of all duties and obligations contained in this Consent Decree, all alleged violations identified in the Administrative Complaint shall be deemed fully resolved. However, nothing herein is intended to relieve Defendant from compliance with the requirements of the Executive Order, Section 503, VEVRA or their regulations, nor to limit OFCCP's right to review Defendant's compliance with such requirements.

7. Defendant agrees that there will be no retaliation of any kind against any beneficiary of this Consent Decree, or against any person who has provided information or assistance in connection with this Decree.

8. This Consent Decree does not constitute an admission by Layton of discrimination on the basis of sex against any individual applicant. Nor does defendant admit a failure to make good faith efforts to comply with the terms of the Conciliation Agreement entered into on May 10, 1990.

Part B. Jurisdiction and Procedural History

9. In its initial compliance review of Layton Construction in March 1990, OFCCP identified 13 affirmative action violations.

10. On May 10, 1990 OFCCP and Defendant entered into a Conciliation Agreement, at which point Defendant had already remedied 10 of the 13 affirmative action violations.

11. The three remaining violations which Defendant was obligated to correct under the Conciliation Agreement included: (1) Layton's failure to maintain a current list of minority and female recruitment sources and to notify such sources of its employment opportunities; (2) Layton's failure to list all available employment openings with the State Employment Service; and (3) Layton's failure to make good faith efforts to meet the nationally established construction craft goal of 6.9% for women in the laborer, carpenter helper, carpenter, and equipment operator crafts.

12. In addition, the Conciliation Agreement obligated Defendant to submit two semi-annual reports to OFCCP so that it could monitor the company's compliance with the terms of the Conciliation Agreement. After Defendant submitted the first of the two reports, OFCCP determined that Defendant failed to comply with the three provisions of the conciliation agreement designed to correct the deficiencies outlined in ¶11, *supra*. Specifically, OFCCP found that Defendant had failed to provide certain recruitment sources with timely notice of its employment opportunities; failed to list all employment openings with the state employment service; and failed to make good faith efforts to recruit and consider qualified women in construction craft positions.

13. In addition, as part of this follow-up investigation OFCCP identified four female applicants (Becky Reynolds, Patricia Stamp, LaDee Scott and Kristi Bateman) for the laborer positions who it believed to be equally, if not more, qualified than the males hired as laborers during the same period.

Part C. Specific Provisions

1. Job Offers

The parties desire to enter into a just and reasonable resolution of this matter without further proceedings. To that end, they have negotiated in good faith and have executed this Consent Decree with the following specific provisions.

14. On May 19, 1993, as part of the terms of settlement under this Consent Decree, Layton sent by certified mail job offers to LaDee Scott and Becky Reynolds. On May 25, 1993, Layton sent by certified mail a job offer to Partricia Stamp. OFCCP determined that Kristi Bateman was not interested in a job with Layton Construction and thus Layton did not extend an offer to Ms. Bateman. The job offers included job title, rate of pay, job site, description of job benefits, start date, expected duration of the job and time in which to respond to the employment offer. The terms of these offers of employment were acceptable to OFCCP.

2. Back Pay

15. Within 10 days of the effective date of this agreement Layton will submit by certified mail a certified check to Ms. Becky Reynolds Otterstrom in the amount of $3097.29, minus legal payroll deductions, at the following address: 653 West 550 North, Clearfield, Utah 84015. This settlement payment resolves back wages to Ms. Otterstrom for the period April 24, 1990, to June 30, 1993. Within 10 days of the effective date of this agreement, Layton will submit a certified check payable to LaDee Scott in the amount of $885.35, minus legal payroll deductions as determined by her W–4 tax form, at the following address: 144 East 400 South, Spanish Fork, Utah 84660. This settlement payment resolves back wages to Ms. Scott for the period July 18, 1990 to June 30, 1993.

16. Layton will submit confirmation of payment of the settlement back wage awards specified in paragraph 15 of this Decree, including the addresses to which the checks were sent, the amounts of the checks and the dates on which the checks were mailed, to: U.S. Department of Labor, Office of the Solicitor, Division of Civil Rights, 200

Constitution Avenue NW., room N–2464, Washington, DC 20210, within 10 days after such payment has been made.

3. Debarment Period

17. Defendant agrees that it will be barred from bidding for or entering into future Government contracts, subcontracts or Federally assisted construction contracts for a period of ninety days from the effective date of this Consent Decree. This ninety day debarment period shall be effective against Defendant and its officers, agents, servants, employees, successors, divisions and subsidiaries and those persons in active concert or participation with them.

18. Notice of the debarment shall be printed in the Federal Register. In addition, OFCCP shall notify the Comptroller General of the United States General Accounting Office and all Federal Contracting Officers that Defendant is ineligible for the award of any Government contracts, subcontracts or Federally assisted construction contracts.

19. The debarment shall be lifted at the conclusion of the ninety day period once Defendant satisfies the Director of OFCCP that it is in compliance with ¶ 20 below.

20. In order to satisfy the Director of OFCCP that it is in compliance with the Executive Order, Section 503, VEVRA and their implementing regulations, Defendant must accomplish each of the following, without any departure from the stated terms:

a. Layton must list all craft and laborer employment opportunities with the State Employment Service.

b. Layton must provide notification to recruitment sources as soon as defendant is aware of employment openings. Layton provided OFCCP with a list of recruitment sources, from which they specifically request female applicants, in fulfillment of its obligations under the conciliation agreement. (See Attachment B hereto). Layton must contact these sources when an opening is available.

c. Layton agrees to provide three monthly reports to the OFCCP Salt Lake City District Office, Ten West Broadway, Suite 305, Salt Lake City, Utah, 84101. Each report will include the following:

1. A list, for laborers and for each craft, of the number of openings during each one-month period;

2. A list, for laborers and for each craft, of the total number of applications and the total number of female applications received in each one-month period;

3. Verification for laborers and for each craft that the above openings were referred to the State Employment Service and the recruitment sources outlined in ¶20 b. above in each one-month period. Defendant may verify recruitment efforts by documenting a continuing request for craft/laborer employees from the recruitment sources listed on Attachment B; and

4. A list, for laborers and for each craft, of the total number of hires and the total number of female hires in each one-month period.

d. The first report will be due 30 days after the effective date of this Consent Decree. The second report will be due 60 days after the effective date of this Consent Decree. The third report will be due 90 days after the effective date of this Decree.

e. If there is disagreement between Layton and OFCCP over the proper format of information in ¶ 20c, defendant will have the opportunity to resubmit the information in a format acceptable to OFCCP. Layton will not be found to be out of compliance solely due to the format of the information provided to OFCCP.

21. The OFCCP Salt Lake City District Office shall review each of Defendant's monthly reports and shall determine whether Defendant has complied with the terms of ¶ 20 of this Consent Decree. OFCCP shall notify Defendant in writing, within 10 days of receipt of each report, if there is a deficiency.

22. If OFCCP finds that Defendant has complied with the terms of this Consent Decree, the debarment shall be lifted after the ninety day period and Defendant shall be free to enter into future Government contracts, subcontracts and Federally assisted construction contracts. OFCCP will notify Defendant in writing within 10 days of the last report whether it will be reinstated. Notice of the reinstatement shall be printed in the **Federal Register** and shall be made to the Comptroller General of the General Accounting Office and all Federal Contracting Officers.

23. If OFCCP's Salt Lake City District Office finds that Defendant has not complied with the terms of the Consent Decree, OFCCP will notify Defendant in writing within 10 days of the last report that the debarment shall not be lifted. The debarment shall remain in effect until Defendant submits to the OFCCP Salt Lake City District Office three consecutive acceptable monthly reports containing the information set out in ¶ 20c which demonstrates that it is in compliance with the Consent Decree, the Executive Order, Section 503, VEVRA and their implementing regulations. The first report shall be submitted 30 days after issuance of OFCCP's notice that the debarment will not be lifted. Additional reports, if necessary, shall be filed every 30 days thereafter.

24. OFCCP shall notify Defendant in writing, once it is in compliance for three consecutive months pursuant to ¶ 23, above, that its obligations under the Consent Decree are fulfilled and that the debarment will be lifted.

25. Defendant may file a motion with the Administrative Law Judge for review of the Director's decision and Defendant may request a hearing at which the sole issue will be whether Defendant has complied with the terms of this Consent Decree.

Part D. Implementation and Enforcement of the Decree

26. Jurisdiction, including the authority to issue any additional orders or decrees necessary to effectuate the implementation of the provisions of this Consent Decree, is retained by the Office of Administrative Law Judges for a period of nine months from the date this Consent Decree becomes final. If any motion is pending before the Office of Administrative Law Judges nine months from the date this Consent Decree becomes final, jurisdiction shall continue beyond nine months and until such time as the pending motion is finally resolved.

27. If any time during the nine months OFCCP believes that Defendant has violated any portion of this Consent Decree, Defendant will be promptly notified of that fact in writing. This notification will include a statement of the facts and circumstances relied upon in forming that belief. In addition, the notification will provide Defendant with 15 days to respond in writing except where OFCCP alleges that such a delay would result in irreparable injury.

28. Enforcement proceedings for violation of this Consent Decree may be initiated at any time after the 15-day period referred to in paragraph 27 has elapsed (or sooner, if irreparable injury is alleged) upon filing with the Court a motion for an order of enforcement and/or sanctions. The issues in a hearing on the motion shall relate solely to the issues of the factual and legal claims made in the motion.

29. Liability for violation of this Consent Decree shall subject Defendants to sanctions set forth in the Executive Order, Section 503, VEVRA and their implementing regulations and other appropriate relief, including further debarment.

30. If an application or motion for an order of enforcement or clarification indicates in writing that the application or motion is unopposed by the plaintiff

or defendant, as appropriate, the application or motion may be presented to the Court without hearing and the proposed Order may be implemented immediately. If an application or motion is opposed by any party, the party in opposition shall file a written response within twenty (20) days of service. The Office of Administrative Law Judges may, if it deems it appropriate, schedule an oral hearing on the application or motion.

31. The Agreement, herein set forth, is hereby approved and shall constitute the final Administrative Order in this case.

It is so ordered, this 1st day of November, 1993.

John M. Vittoner,
Administrative Law Judge, U.S. Department of Labor.

So Agreed.

On Behalf of Layton Construction Company, Inc.

Dated: August 31, 1993.

Darwin Millet,
Vice-President Administration, Layton Construction Company.

On Behalf of the Office of Federal Contract Compliance Programs.

Thomas S. Williamson, Jr.,
Solicitor of Labor.

James D. Henry,
Associate Solicitor.

Heidi Dalzell-Finger,
Acting Counsel for Litigation.

Beverly Dankowitz,
Attorney.

Dated: September 2, 1993.

L. Denise Galambos,
Attorney.

U.S. Department of Labor, room N–2464, 200 Constitution Ave., NW., Washington, DC 20210, (202) 219–5854.

Conciliation Agreement Between U.S. Department of Labor Office of Federal Contract Compliance Programs and Layton Construction Company, Inc., 2987 South 300 West, Salt Lake City, Utah 84115

Part I: General Provisions

1. This Agreement is between the Office of Federal Contract Compliance Programs (hereinafter OFCCP) and Layton Construction Company, Inc. (hereinafter Layton).

2. The problem areas identified in this Agreement were found during the compliance review of Layton which commenced March 14, 1990. OFCCP alleges that Layton has violated Executive Order 11246, as amended, 38 U.S.C. 2012, as amended (Vietnam Era Veterans Readjustment Assistance Act of 1974), Section 503 of the Rehabilitation Act of 1973, as amended, and their implementing regulations at 41 CFR chapter 60 by failing to comply with the regulations cited in Part II (Specific Provisions) of this Agreement.

3. This Agreement does not constitute an admission by Layton of any violation of Executive Order 11246, as amended, 38 U.S.C. 2012, as amended (Vietnam Era Veterans Readjustment Assistance Act of 1974), Section 503 of the Rehabilitation Act of 1973, as amended, and their implementing regulations. The provisions of this Agreement will become part of Layton's Affirmative Action Programs.

Subject to the performance by Layton of all promises and representations contained herein and in its Affirmative Action Programs, all identified problem areas in this Agreement in regard to the compliance of Layton with Executive Order 11246, as amended, 38 U.S.C. 2012, as amended, Section 503 of the Rehabilitation Act of 1973, as amended, and their implementing regulations, shall be deemed resolved. However, Layton is advised that the commitments contained in this Agreement do not preclude future determinations of noncompliance based on a finding that the commitments are not sufficient to achieve compliance.

4. Layton agrees that OFCCP may review compliance with this Agreement. As part of such review, OFCCP may require written reports, inspect the premises, examine witnesses, and examine and copy documents, as may be relevant to the matter under investigation and pertinent to Layton's compliance. Layton shall permit access to its premises during normal business hours for these purposes.

5. Nothing herein is intended to relieve Layton from compliance with the requirement of Executive Order 11246, as amended, 38 U.S.C. 2012, as amended, Section 503 of the Rehabilitation Act of 1973, as amended, and their implementing regulations.

6. Layton agrees that there will be no retaliation of any kind against any beneficiary of this Agreement, or against any person who has provided information or assistance, or who files a charge or who participates in any manner in any proceeding under Executive Order 11246, as amended, 38 U.S.C. 2012, as amended, and Section 503 of the Rehabilitation Act of 1973, as amended, or any other equal employment statute or Executive Order.

7. This Agreement will be deemed to have been accepted by the Government on the date of signature by the District Director unless it has been disapproved by the Director, OFCCP, within 45 days of the Director's receipt of the Agreement.

8. (a) If, at any time in the future, OFCCP believes that Layton has violated any portion of this Agreement, Layton will be promptly notified of that fact in writing. This notification shall include a statement of the facts and circumstances relied upon in forming that belief. In addition, the notification will provide Layton with 15 days from receipt of the notification to respond in writing, except where OFCCP alleges that such delay would result in irreparable injury.

(b) It is understood that enforcement proceedings for violation of this Agreement may be initiated at any time after the 15-day period has elapsed (or sooner if irreparable injury is alleged) without issuance of a show cause notice.

(c) It is recognized that where OFCCP believes that Layton has breached the conciliation agreement, evidence regarding the entire scope of Layton's alleged noncompliance from which the conciliation agreement resulted, in addition to evidence regarding Layton's alleged violation of the conciliation agreement, may be introduced at the enforcement proceeding.

(d) It is further recognized that liability for violation of this Agreement may subject Layton to sanctions set forth in Section 209 of the Executive Order and/or appropriate relief, or to the sanctions set forth in 41 CFR 60–250.28 and 41 CFR 60–741.28.

Part II: Specific Provisions

1. *Problem Area:* Layton has failed to include or to otherwise reference the equal opportunity clause in its non-exempt purchase orders. This is a requirement of 41 CFR 60–1.4(a)(7).

Remedy: On April 19, 1990, Layton submitted a revised purchase order form which references the equal opportunity clause. This submission was found acceptable by OFCCP and met the requirements of 41 CFR 60–1.4(a)(7). Layton will not repeat this deficiency.

2. *Problem Area:* Layton has failed to notify OFCCP of the award of non-exempt subcontracts. This is a requirement of 41 CFR 60–4.2(d)3.

Remedy: On March 16, 1990, and April 19, 1990, Layton submitted a list of its current non-exempt subcontracts and committed to notify OFCCP of the award of future non-exempt subcontracts. This notice shall include the name, address, and telephone number of the subcontractor, employer identification number of the subcontractor, estimated dollar amount of the subcontract, estimated starting and ending dates of the subcontract, and the geographical area in which the subcontract is to be performed. This

submission and commitment were found acceptable by OFCCP and met the requirements of 41 CFR 60–4.2(d)3. Layton will not repeat this deficiency.

3. *Problem Area:* Layton has failed to maintain a current list of minority and female recruitment sources and to notify such sources of its employment opportunities. This is a requirement of 41 CFR 60–4.3(a)7.b.

Remedy: On April 19, 1990, Layton submitted a current list of minority and female recruitment sources and committed to provide timely notification to such sources when it has employment opportunity. This submission and commitment were found acceptable by OFCCP and met the requirements of 41 CFR 60–4.3(a)7.b. Layton will not repeat this deficiency.

4. *Problem Area:* Layton has failed to thoroughly address the requirements of 41 CFR 60–4.3(a)7.f. Specifically, Layton has failed to develop an EEO policy, to review this policy with its supervisory personnel and employees, and to post its policy where it is accessible to all employees.

Remedy: On April 19, 1990, Layton submitted its EEO policy and evidence of the dissemination of this policy. This submission was found acceptable by OFCCP and met the requirements of 41 CFR 60–4.3(a)7.f. Layton will not repeat this deficiency.

5. *Problem Area:* Layton has failed to review its EEO policy and affirmative action obligations at least annually with its supervisory personnel. This is a requirement of 41 CFR 60–4.3(a)(7.g.

Remedy: On April 19, 1990, Layton submitted evidence of the review of its EEO policy and affirmative action obligations with its supervisory personnel, and committed to continue such review at least annually. This submission and commitment were found acceptable by OFCCP and met the requirements of 41 CFR 60–4.3(a)7.g. Layton will not repeat this deficiency.

6. *Problem Area:* Layton has failed to conduct an inventory and evaluation of all minority and female employees for promotion potential at least annually. This is a requirement of 41 CFR 60–4.3(a)7.1.

Remedy: On April 19, 1990, Layton submitted evidence of the review of its minority and female employees' promotion potential, and committed to continue and review at least annually. This submission and commitment were found acceptable by OFCC and meet the requirements of 41 CFR 60–4.3(a)7.1. Layton will not repeat this deficiency.

7. *Problem Area:* Layton has failed to review its supervisors' adherence to and performance under its eeo policies and affirmative action obligations at least annually. This is a requirement of 41 CFR 60–4.3(a)7.p.

Remedy: On April 19, 1990, Layton submitted evidence of the review of its supervisors' adherence to and performance under its eeo policies and affirmative action obligations, and committee to continue such review at least annually. This submission was found acceptable by OFCCP and met the requirements of 41 CFR 60–4.3(a)7.p. Layton will not repeat this deficiency.

8. *Problem Area:* Layton has failed to adequately demonstrate every good faith effort in meeting the nationally established construction craft goal of 6.9% for women in the laborer, carpenter helper, carpenter, and equipment operator crafts. It is noted that during the review period Layton experienced employment vacancies in the laborer, carpenter helper, and carpenter crafts. The nationally established construction craft goal for women is a requirement of 41 CFR 60–4.6, Appendix A.

Remedy: On April 19, 1990, Layton agreed to make every good faith effort in order to recruit and consider qualified women for its employment opportunities. Such efforts will include but not be limited to provided notice to female recruitment sources of employment opportunities. Layton has also agreed to enter into voluntary linkage agreements with the Salt Lake City Job Service Center and Salt Lake Community College Placement Office for the purpose of increasing its recruitment of qualified female applicants. This agreement was found acceptable by OFCCP and met the requirements of 41 CFR 60–4.6, Appendix A. Layton will not repeat this deficiency.

9. *Problem Area:* Layton has filed to list all suitable employment openings with the State employment service. This is a good requirement of 41 CFR 60–250.4 (b) and (h).

Remedy: On April 19, 1990, Layton committed to list all suitable employment openings with the State employment service. This commitment was found acceptable to OFCCP and met the requirements of 41 CFR 60–250.4 (b) and (h). Layton will not repeat this deficiency.

10. *Problem Area:* Layton has failed to include the affirmative action clauses in its non-exempt purchase orders. This is a requirement of 41 CFR 60–250.4(m) and 41 CFR 60–741.4(f).

Remedy: On April 19, 1990, Layton submitted a revised purchase/order form which references the affirmative action clauses. This submission was found acceptance by OFCC and met the requirements of 41 CFR 660–250.4(m) and 41 CFR 60–741.4(f). Layton will not repeat this deficiency.

11. *Problem Area:* Layton has failed to develop, implement, and maintain current year affirmative action programs are required by 38 USC 2012, as amended (Vietnam Era Veterans' Readjustment Assistant Act of 1974), Section 503 of the Rehabilitation Act of 1973, as amended, and their implementing regulations at 41 CFR 60–250.5(a), 41 CFR 60–250.6, 41 CFR 60–741.5(a), and 41 CFR 60–741.6.

Remedy: On April 19 and 25, 1990, Layton submitted current year affirmative action programs which address the requirements of the Vietnam Era Veterans Readjustment Assistance Act of 1974, as amended, and Section 503 of the Rehabilitation Act of 1973, as amended. This submission was found acceptable by OFCCP and met the requirements of 41 CFR 60–250(a), 41 CFR 60–250.6, 41 CFR 60–741.5(a), 41 CFR 60–741.6. Layton will not repeat this deficiency.

12. *Problem Area:* Layton has failed to post the location and hours during which its full affirmative action programs are available for inspection. This is a requirement of 41 CFR 250.5(c) and 41 CFR 60–741.5(d).

Remedy: On April 19, 1990, Layton submitted evidence that it has posted the availability of its full affirmative action programs for inspection. This submission was found acceptable by OFCCP and met the requirements of 41 CFR 60–250.5(c) and 41 CFR 60–741.5(d). Layton will not repeat this deficiency.

13. Problem Area: Layton has failed to issue an investigation to self-identify to its employees and applicants for employment. This is a requirement of 41 CFR 60–250.5(d) and 41 CFR 60–741.5(c)(1).

Remedy: On April 19, 1990, Layton submitted evidence that it has offered an invitation to self-identify to its employees and applicants for employment. This submission was found acceptable by OFCCP and met the requirements of 41 CFR 60–250.5(d) and 41 CFR 60–741.5(c)(1). Layton will not repeat this deficiency.

Part III: Reporting Requirements

Layton agrees to provide two reports to the Salt Lake City District Office, OFCCP, which will include the following:

a. List for each craft the number of contacts with linkage and other recruitment sources

b. List for each craft the number of applications and the number of female applications received

c. List for each craft the number of hires and the number of female hires made

d. List for each craft the number of regular and overtime hours worked and the number of regular and overtime hours worked by women.

The first report will be due November 12, 1990, and will cover the period of May 1, 1990 through October 31, 1990.

The second report will be due May 10, 1990 and will cover the period of November 1, 1990, through April 30, 1991.

This Agreement will terminate one year from the date of signature of the District Director, OFCCP.

Part IV: Signatures

This Conciliation Agreement is hereby executed by and between the Office of Federal Contract Compliance Programs and Layton Construction, Company, Inc., 2987 South 300 West, Salt Lake City,Utah.

Dated: May 8, 1990.

Allan Layton,

President.

Layton Construction Co., Inc., 2987 South 300 West, Salt Lake City, Utah 84115.

Dated: May 10, 1990.

Christina Anderson,

Equal Opportunity Specialist.

Office of Federal Contract, Compliance Programs, Salt Lake City, Utah.

Dated: May 10, 1990.

Joseph Gallegos Jr.,

District Director, Office of Federal Contract Compliance Programs.

Attachment B

To: Christina Anderson, Equal Opportunity Specialist

From: Darwin D. Millet, Equal Employment Officer, Layton Construction Co., Inc.

Subject: Compliance With EEO Audit of March 14th, 15th & 16th.

During your compliance audit last month you outlined a number of areas that needed improvement or formalization to conform to EEO regulations. This memo, and the enclosures, should respond entirely to those areas. If you have further concerns do not hesitate to call.

1. In compliance with 41 CFR 60–4.2(d)3 we will notify the Office of Federal Contract Compliance of all non-exempt subcontracts on U.S.-government funded projects in the future.

We understand that this notification must be made within 10 days of award of any subcontract in excess of $10,000.00.

2. The recruitment sources we are currently using are:

Utah Department of Employment Security, 1234 South Main Street, 533–2698

Rae Wall, Employer Relations Representative

Off the street applicants.

Deseret News and Salt Lake Tribune Employee Referrals

Note: As the audit showed we have close to 50% minority participation in our trades. We have visited with Job Service and feel confident we can find qualified handicapped and women candidates through them, the newspapers and employee referrals.

In compliance with 41 CFR 60–4.3(a)(7)(b) we will maintain the above list of recruitment sources and document any responses from them.

3. Enclosed is the formal Equal Employment Opportunity Policy Statement for Layton Construction. Further, in compliance with 41 CFR 60–3(a)(7)(f) this policy is being posted at each job site and at the home office.

4. In compliance with 41 CFR 60–4(a)(7)(g) all supervisory personnel will review and be instructed in the company's EEO Policy and their Affirmative Action Plan.

The meetings are scheduled as follows:

April 18th Wednesday: All construction site supervisors

April 20th Friday: All construction office managers

April 23th Monday: All executive and office management

Meeting Agenda

I. Discussion on the laws prohibiting discrimination.

A. Define protected groups and what constitutes discrimination. Handicapped Workers, Disabled Veterans, Veterans of the Vietnam Era, Age, Sex, Equal Pay.

II. Discussion of the company's EEO Policy & Affirmative Action Plan.

III. Discussion of how to implement the AA Plan and how to avoid and investigate discrimination issues.

5. In compliance with 41 CFR 60–4.4(a)(7)(j) We have posted the enclosed NOTICE FOR REFERRALS at all of our jobsites and in the home office.

6. Our Affirmative Action Plan indicates that we will annually evaluate and prepare an inventory of minority, female and handicapped persons for promotional opportunities. This evaluation will be documented on the enclosed form entitled "ANNUAL INVENTORY AND EVALUATION". See 41 CFR 60–4.3(a)(7)(1).

7. In compliance with 41 CFR 60–4.3(a)(7)(p) annually the EEO officer will review the performance of all supervisory personnel regarding their adherence to the company's EEO policy and Affirmative Action plan. This review will be completed within the calendar year. See enclosed form "ANNUAL EVALUATION OF SUPERVISORS'/FOREMEN'S ADHERENCE TO EEO POLICY AND AFFIRMATIVE ACTION PLAN".

8. As indicated in our Affirmative Action Plan all suitable employment openings (at a salary of less than $25,000 per year) will be listed at the local office of the Utah Department of Employment Security. I have already met with them and initiated this procedure. See 41 CFR 60–250.4(b).

9. The following clause will be added to all Purchase Orders in excess of $10,000.00 on all federally assisted projects: "Layton Construction Co., Inc. is an Equal Opportunity Employer. All suppliers and vendors are hereby notified that you are subject to the provisions of 41 CFR 60–1.4(a)(7), 41 CFR 60–1.8(b), 41 CFR 60–250.4(m), and 41 CFR 60–741.4(f)."

10. Enclosed is our Affirmative Action Plan per CFR 60–250.5(c).

11. Our EEO Policy statement (see enclosed) includes a paragraph noting the availability of our Affirmative Action Plan for inspection per 41 CFR 60–250.5(c).

12. Enclosed is our "INVITATION TO SELF IDENTIFY" form which is included with each application effective immediately. See 41 CFR 60–250.5(d) and 41 CFR 60–741.5(c)(1).

I believe the above actions will now put us into compliance. The actual execution of these procedures has already begun.

Thank you for reviewing this memo and noting our compliance status.

Service Sheet

Case Name: Layton Construction Company

Case No.: 93–OFC–17

Title of Document: Decision and Order

A copy of the above-entitled document was mailed November 1, 1993, to the following individuals:

Director, Office of Administrative Appeals, U.S. Department of Labor, room S–4309, 200 Constitution Avenue, NW., Washington, DC 20210.

Solicitor of Labor, U.S. Department of Labor, room S–2002, FPB, 200 Constitution Avenue, NW., Washington, DC 20210.

Darwin Millet, Layton Construction Co., Inc., 2987 South 300 West, Salt Lake City, UT 84115.

James D. Henry, Associate Solicitor, Civil Rights Division, U.S.

Department of Labor, room N–2464, 200 Constitution Avenue, NW., Washington, DC 20210.

Tedrick A. Housh, Esquire, Regional Solicitor, U.S. Department of Labor, 2106 Federal Office Building, 911 Walnut Street, Kansas City, MO 64106.

Special Counsel to the Asst. Secretary of Labor, U.S. Department of Labor, ETA, room N–4671, 200 Constitution Avenue, NW., Washington, DC 20210.

Office of Federal Contract Compliance Programs, U.S. Department of Labor, room C–3325, 200 Constitution Avenue, NW., Washington, DC 20210.

Joseph Gallegos, Jr., District Director, Office of Federal Contract Compliance Programs, suite 305, 10 West Broadway, Salt Lake City, UT 84101.

Juanita Prophet,

Paralegal.

[FR Doc. 93–28756 Filed 11–22–93; 8:45 am]

BILLING CODE 4510–27–M

NUCLEAR REGULATORY COMMISSION

[Docket No. 50–409]

Dairyland Power Cooperative, La Crosse Boiling Water Reactor; Environmental Assessment and Finding of No Significant Impact

The U.S. Nuclear Regulatory Commission is considering issuance of an exemption from the revised 10 CFR 50.120 requirements of the Code of Federal Regulations to the Dairyland Power Cooperative (the licensee) for the La Crosse Boiling Water Reactor (LACBWR), pursuant to 10 CFR 50.12.

Environmental Assessment

Identification of Proposed Action

The proposed action would grant an exemption from the training requirements of 10 CFR 50.120. By letter dated July 26, 1993, the licensee identified the special conditions that exist at LACBWR as the basis for their exemption request.

The Need for the Proposed Action

LACBWR is permanently shutdown, defueled, and in SAFSTOR. All the La Crosse spent fuel has been transferred to the spent fuel pit. This exemption would relieve the licensee from the training requirements of 10 CFR 50.120. However, it does not relieve the licensee from previous requirements or commitments to train and qualify facility personnel.

Environmental Impacts of the Proposed Action

The proposed exemption from the requirements of 10 CFR 50.120 does not have any effect on accident risk and the possibility of environmental impact is extremely remote.

The nuclear fuel is stored in the spent fuel pit, and the accidents previously analyzed in the NRC approved Decommissioning Plan demonstrated there are no credible accident scenarios that could result in offsite doses greater than a small fraction of the U.S. Environmental Protection Agency's "Protective Action Guidelines." The proposed action does not increase the probability or consequences of any accidents, no changes are being made in the types of any effluent that may be released offsite, and there is no change in the allowable individual or cumulative occupational radiation exposures on-site. Accordingly, the NRC concludes that this proposed action would result in no significant radiological environmental impact.

With regard to potential non-radiological impacts, the proposed action does not affect non-radiological plant effluents and has no other environmental impact. Therefore, the NRC concludes that there are no significant non-radiological environmental impacts associated with the proposed action.

Alternatives to the Proposed Action

Since the NRC staff has concluded that there are no significant environmental effects that would result from the proposed action, any altneratives with equal or greater environmental impacts need not be evaluated.

Alternative Use of Resources

This action does not involve the use of any resources not previously considered in the Supplement to the Environment Report for LACBWR.

Agencies and Persons Consulted

The NRC staff reviewed the exemption request. No other agencies or personnel were contacted.

Finding of No Significant Impact

Based upon this environmental assessment, the staff concludes that the proposed action will not have a significant effect on the quality of the human environment. Therefore, the NRC will not prepare an environmental impact statement for the proposed exemption.

For further details with respect to this action, the licensee's letter dated July 26, 1993, and the NRC staff's Safety Evaluation, included in the exemption, are available for public inspection at the NRC's Public Document Room, the Gelman Building, 2120 L Street, NW., Washington, DC 20037, and at the local public document room at the La Crosse Public Library, 800 Main Street, La Crosse, WI 54601.

Dated at Rockville, Maryland, this 17th day of November, 1993.

For the Nuclear Regulatory Commission.

John H. Austin,

Chief, Decommissioning and Regulatory Issues Branch, Division of Low-Level Waste Management and Decommissioning, Office of Nuclear Material Safety and Safeguards

[FR Doc. 93–28746 Filed 11–22–93; 8:45 am]

BILLING CODE 7590–01–M

[Docket No. 50–16]

Detroit Edison Co., Enrico Fermi Atomic Power Plant, Unit 1; Environmental Assessment and Finding of No Significant Impact

The U.S. Nuclear Regulatory Commission is considering issuance of an exemption from the revised 10 CFR 50.120 requirements of the Code of Federal Regulations to the Detroit Edison Company (the licensee) for the Enrico Fermi Atomic Power Plant, Unit 1 (Fermi-1), pursuant to 10 CFR 50.12.

Environmental Assessment

Identification of Proposed Action

The proposed action would grant an exemption from the training requirements of 10 CFR 50.120. By letter dated July 30, 1993, the licensee identified the special circumstances that exist at the Firmi-1 as the basis for their exemption request.

The Need for the Proposed Action

Fermi-1 is a permanently shutdown sodium cooled, fast breeder reactor in SAFSTOR. The fuel and uranium-238 blanket material have been removed and shipped offsite. A possession-only licensee was issued on September 5, 1973. The exemption would relieve the licensee from the training requirement of 10 CFR 50.120. However, it does not relieve the licensee from previous requirements or commitments to train and qualify facility personnel.

Environmental Impacts of the Proposed Action

The proposed exemption would not have any effect on accidents previously analyzed in the Fermi-1 Supplemental Environmental Information, September 1975. The reactor has been defueled and the nuclear fuel has been shipped offsite. Based on the conditions at

Fermi-1, there are no credible accident scenarios that could result in offsite doses that would exceed a small fraction of the U.S. Environmental Protection Agency's "Protective Action Guidelines."

The proposed action would not change the types of effluent that may be released offsite, and there would be no significant increase in the allowable individual or cumulative occupational radiation exposures on-site. Accordingly, the NRC concludes that this proposed action would result in no significant radiological environmental impact.

With regard to potential non-radiological impacts, the proposed action does not affect non-radiological plant effluents and has no other environmental impact. Therefore, the NRC concludes that there are no significant non-radiological environmental impacts associated with the proposed action.

Alternatives to the Proposed Action

Since the NRC staff has concluded that there are no significant environmental effects that would result from the proposed action, any alternatives with equal or greater environmental impacts need not be evaluated.

Alternative Use of Resources

This action does not involve the use of any resources not previously considered in the Fermi-1 Supplemental Environmental Information.

Agencies and Persons Consulted

The NRC staff reviewed the exemption request. No other agencies or personnel were contacted.

Finding of No Significant Impact

Based upon this environmental assessment, the staff concludes that the proposed action will not have a significant effect on the quality of the human environment. Therefore, the NRC will not prepare an environmental impact statement for the proposed exemption.

For further details with respect to this action, the licensee's letter dated July 30, 1993, and the NRC staff's Safety Evaluation, included in the exemption, are available for public inspection at the NRC's Public Document Room, the Gelman Building, 2120 L Street, NW., Washington, DC 20037, and at the local public document room at the Monroe County Library System, 3700 South Custer Road, Monroe, MI 48161.

Dated at Rockville, Maryland, this 17th Day of November, 1993.

For the Nuclear Regulatory Commission.

John H. Austin,

Chief, Decommissioning and Regulatory Issues Branch, Division of Low-Level Waste Management and Decommissioning, Office of Nuclear Material Safety and Safeguards.

[FR Doc. 93–28748 Filed 11–22–93; 8:45 am]

BILLING CODE 7590–01–M

[Docket No. 50–18]

General Electric Co., Vallecitos Boiling Water Reactor; Environmental Assessment and Finding of No Significant Impact

The U.S. Nuclear Regulatory Commission is considering issuance of an exemption from the revised 10 CFR 50.120 requirements of the Code of Federal Regulations to the General Electric Company (the licensee) for the Vallecitos Boiling Water Reactor (VBWR), pursuant to 10 CFR 50.12.

Environmental Assessment

Identification of Proposed Action

The proposed action would grant an exemption from the training requirements of 10 CFR 50.120. By letter dated July 18, 1993, the General Electric Company (GE) identified the special conditions that exist at the VBWR as the basis for this exemption request.

The Need for the Proposed Action

VBWR is a 50 MW boiling water reactor that permanently ceased power operations in 1962. The nuclear fuel has been removed from the reactor and shipped offsite. VBWR was issued a possession-only license in 1965 and the plant is currently in SAFSTOR until the year 2016. An exemption would relieve the licensee from the training requirements of 10 CFR part 50.120, which are not applicable at a reactor that has no nuclear fuel on site and that is in SAFSTOR. However, an exemption from the requirement of 10 CFR 50.120 does not relieve the licensee from previous requirements or commitments to train and qualify facility personnel.

Environmental Impacts of the Proposed Action

The proposed exemption from the requirements of 10 CFR 50.120 does not have any effect on accidents previously analyzed in the NRC approved "Final Report on Deactivation of the Vallecitos Boiling Water Reactor." There is no nuclear fuel on site and there are no credible accident scenarios that could result in offsite doses that would exceed a small fraction of the U.S. Environmental Protection Agency's "Protective Action Guidelines." The proposed action does not increase the probability or consequences of any accidents, no changes are being made in the types of any effluent that may be released offsite, and there is no change in the allowable individual or cumulative occupational radiation exposures on-site. Accordingly, the NRC concludes that this proposed action would result in no significant radiological environmental impact.

With regard to potential non-radiological impacts, the proposed action does not effect non-radiological plant effluents and has no other environmental impact. Therefore, the NRC concludes that there are no significant non-radiological environmental impacts associated with the proposed action.

Alternatives to the Proposed Action

Since the NRC has concluded that there are no significant environmental effects that would result from the proposed action, any alternatives with equal or greater environmental impacts need not be evaluated.

Alternative Use of Resources

This action does not involve the use of any resources not previously considered for VBWR.

Agencies and Persons Consulted

The NRC staff reviewed the exemption request. No other agencies or personnel were contacted.

Finding of No Significant Impact

Based upon this environmental assessment, the staff concludes that the proposed action will not have a significant effect on the quality of the human environment. Therefore, the NRC will not prepare an environmental impact statement for the proposed exemption.

For further details with respect to this action, the licensee's letter dated July 18, 1993, and the NRC staff's Safety Evaluation, included in the exemption, are available for public inspection at the NRC's Public Document Room, the Gelman Building, 2120 L Street, NW., Washington, DC 20037.

Dated at Rockville, Maryland, this 17th day of November, 1993.

For the Nuclear Regulatory Commission.

John H. Austin,

Chief, Decommissioning and Regulatory Issues Branch, Division of Low-Level Waste Management and Decommissioning, Office of Nuclear Material Safety and Safeguards.

[FR Doc. 93–28744 Filed 11–22–93; 8:45 am]

BILLING CODE 7590–01–M

[Docket No. 50–322]

Long Island Power Authority, Shoreham Nuclear Power Station; Environmental Assessment and Finding of No Significant Impact

The U.S. Nuclear Regulatory Commission is considering issuance of an exemption from the requirements of 10 CFR 50.120 to the Code of Federal Regulations to the Long Island Power Authority (LIPA) or the licensee) for the Shoreham Nuclear Power Station (SNPS) pursuant to the requirements of 10 CFR 50.12.

Environmental Assessment

Identification of Proposed Action

The proposed action would grant an exemption from the training requirements of 10 CFR 50.120. By letter dated August 2, 1993, the licensee requested this exemption.

The Need for the Proposed Action

The SNPS Nuclear Power Station is being dismantled in accordance with the approved SNPS Decommissioning Plan (DP). This exemption would relieve the licensee from the requirements of 10 CFR 50.120 which are not applicable to a reactor that has been defueled, and is being dismantled. However, this exemption does not relieve the licensee from the training requirements or commitments contained in the approved SNPS DP.

Environmental Impacts of the Proposed Action

The proposed exemption will not have any effect on any of the accidents evaluated in the SNPS DP. SNPS is defueled and there are no credible accident scenarios that could result in offsite doses that would exceed a small fraction of the U.S. Environmental "Protection Agency's" Protective Action Guidelines."

Based on the staff's review of the accidents analyzed in the DP and the special circumstances at SNPS, the staff concludes that an exemption from the requirements of 10 CFR part 50.120 would not cause or increase the potential for an accident that would result in a radiological release that differs from those previously analyzed in DP for SNPS. The proposed action would not cause a change in the types of any effluent that may be released offsite, and there would be no change in the allowable individual or cumulative occupational radiation exposures on-site. Accordingly, the NRC staff concludes that this proposed action would result in no significant radiological environment impact.

With regard to potential non-radiological impacts, the proposed action does not affect non-radiological plant effluents and has no other environmental impact. Therefore, the NRC concludes that there are no significant non-radiological environmental impacts associated with the proposed action.

Alternatives to the Proposed Action

Since the NRC concluded that there are no significant environmental effects that would result from the proposed action, any alternatives with equal or greater environmental impacts need not be evaluated.

Alternative Use of Resources

This action does not involve the use of any resources not previously considered in the Final Environmental Statement for SNPS.

Agencies and Persons Consulted

The licensee initiated this exemption. The NRC staff is reviewing the request. The State of New York was contacted, and had no comments.

Finding of No Significant Impact

Based upon this environmental assessment, the NRC staff concludes that the proposed action will not have a significant effect on the quality of the human environment. Therefore, the NRC staff will not prepare an environmental impact statement for the proposed exemption.

For further details with respect to this action, the licensee's application dated August 2, 1993, and the NRC staff's Safety Evaluation, included in the exemption, are available for public inspection at the NRC's Public Document Room, the Gelman Building, 2120 L Street, NW., Washington, DC 20037, and at the local public document room at the Shoreham Wading River Public Library, Shoreham Wading River High School, Route 25A, Shoreham, NY 11792.

Dated at Rockville, Maryland, this 17th day of November, 1993.

For the Nuclear Regulatory Commission.

John H. Austin,

Chief, Decommissioning and Regulatory Issues Branch, Division of Low-Level Waste Management and Decommissioning, Office of Nuclear Material Safety and Safeguards.

[FR Doc. 93–28745 Filed 11–22–93; 8:45 am]

BILLING CODE 7590–01–M

[Docket No. 50–171]

Philadelphia Electric Co., Peach Bottom Atomic Power Station, Unit 1; Environmental Assessment and Finding of No Significant Impact

The U.S. Nuclear Regulatory Commission is considering issuance of an exemption from the revised 10 CFR 50.120 requirements of the Code of Federal Regulations to the Philadelphia Electric Company (the licensee) for the Peach Bottom Atomic Power Station, Unit 1 (PBAPS–1), pursuant to 10 CFR 50.12.

Environmental Assessment

Identification of Proposed Action

The proposed action would grant an exemption from the training requirements of 10 CFR 50.120. By letter dated July 30, 1993, the licensee identified the special conditions that exist at PBAPS–1 as the basis for this exemption request.

The Need for the Proposed Action

PBAPS–1 is a permanently shutdown, high-temperature, gas-cooled reactor that ceased power operations in 1974, and the fuel was removed from the reactor and shipped offsite. A possession-only licensee was issued July 6, 1974. PBAPS–1 is currently in SAFSTOR until 2015. The exemption would relieve the licensee from the training requirements of 10 CFR 50.120. However, it does not relieve the licensee from previous requirements or commitments to train and qualify facility personnel.

Environmental Impacts of the Proposed Action

The proposed action does not have any effect on accident risk and the possibility of environmental impact is extremely remote.

The licensee stated that the reactor was defueled, and the nuclear fuel was shipped offsite. In addition, there are no credible accident scenarios that could result in offsite greater than a small fraction of the U.S. Environmental Protection Agency's "Protection Action Guidelines."

Therefore, the proposed action does not increase the probability or consequences of any accidents, no changes are being made in the types of any effluent that may be released offsite, and there is no significant increase in the allowable individual or cumulative occupational radiation exposures on-site. Accordingly, the NRC concludes that this proposed action would result

in no significant radiological environmental impact.

With regard to potential non-radiological impacts, the proposed action does not effect non-radiological plant effluents and has no other environmental impact. Therefore, the NRC concludes that there are no significant non-radiological environmental impacts associated with the proposed action.

Alternatives to the Proposed Action

Since the NRC has concluded that there are no significant environmental effects that would result from the proposed action, any alternatives with equal or greater environmental impacts need not be evaluated.

Alternative Use of Resources

This action does not involve the use of any resources not previously considered for PBAP–1.

Agencies and Persons Consulted

The NRC staff reviewed the exemption request. No other agencies or personnel were contacted.

Finding of No Significant Impact

Based upon this environmental assessment, the staff concludes that the proposed action will not have a significant effect on the quality of the human environment. Therefore, the NRC will not prepare an environmental impact statement for the proposed exemption.

For further details with respect to this action, the licensee's letter dated July 30, 1993, and the NRC staff's Safety Evaluation, included in the exemption, are available for public inspection at the NRC's Public Document Room, the Gelman Building, 2120 L Street, NW., Washington, DC 20037, and at the local public document room at the State Library of Pennsylvania, Walnut Street and Commonwealth Avenue, Harrisburg, PA 17105.

Dated at Rockville, Maryland, this 17th day of November, 1993.

For the Nuclear Regulatory Commission.

John H. Austin,

Chief Decommissioning and Regulatory Issues Branch, Division of Low-Level Waste Management Decommissioning, Office of Nuclear Material Safety and Safeguards.

[FR Doc. 93–28749 Filed 11–22–93; 8:45 am]

BILLING CODE 7590–01–M

[Docket No. 50–267]

Public Service Company of Colorado, Fort St. Vrain Nuclear Generating Station; Environmental Assessment and Finding of No Significant Impact

The U.S. Nuclear Regulatory Commission is considering issuance of an exemption from the revised 10 CFR 50.120 requirements of the Code of Federal Regulations to the Public Service Company of Colorado (PSC or the licensee) for the Fort St. Vrain (FSV) Nuclear Generating Station, pursuant to 10 CFR 50.12.

Environmental Assessment

Identification of Proposed Action

The proposed action would grant an exemption from the training requirements of 10 CFR 50.120. By letter dated August 9, 1993, the licensee requested this exemption.

The Need for the Proposed Action

The FSV Nuclear Generation Station is being dismantled in accordance with the approved FSV Decommissioning Plan (DP). This exemption would relieve the licensee from the requirements of 10 CFR 50.120 which are not applicable to a reactor that has been defueled, and is being dismantled. However, this exemption would not relieve the licensee from the training requirements or commitments contained in the approved FSV DP.

Environmental Impacts of the Proposed Action

The proposed exemption from the requirements of 10 CFR part 50.120 will not have an impact on any of the accidents evaluated for the FSV DP. The nuclear fuel has been transferred to an Independent Spent Fuel Storage Installation, and there are no credible accident scenarios at the FSV Station that could result in offsite doses that would exceed a small fraction of the U.S. Environmental Protection Agency's "Protective Action Guidelines."

Based on the staff's review of PSC's August 9, 1993, submittal, and previously analyzed accidents in the DP, the staff concludes that an accident with the potential for causing a radiological release from FSV is small. The proposed action does not increase the probability or consequences of any accidents, no changes are being made in the types of any effluent that may be released offsite, and there is no significant increase in the allowable individual or cumulative occupational radiation exposures on-site. Accordingly, the NRC staff concludes that this proposed action would result in no significant radiological environmental impact.

With regard to potential non-radiological impacts, the proposed action does not effect non-radiological plant effluents and has no other environmental impact. Therefore, the NRC staff concludes that there are no significant non-radiological environmental impacts associated with the proposed action.

Alternatives to the Proposed Action

Since the NRC has concluded that there are no significant environmental effects that would result from the proposed action, any alternatives with equal or greater environmental impacts need not be evaluated.

Alternative Use of Resources

This Action does not involve the use of any resources not previously considered in the Supplement to the Environmental Report for FSV.

Agencies and Persons Consulted

The licensee initiated this exemption. The NRC staff has reviewed the request. The State of Colorado was contacted, and did not provide comments.

Finding of No Significant Impact

Based upon this environmental assessment, the NRC staff concludes that the proposed action will not have a significant effect on the quality of the human environment. Therefore, the NRC staff will not prepare an environmental impact statement for the proposed exemption.

For further details with respect to this action, the licensee's application dated August 9, 1993, and the NRC staff's Safety Evaluation, included in the exemption, are available for public inspection at the NRC's Public Document Room, the Gelman Building, 2120 L Street, NW., Washington, DC 20037, and at the local public document room at the Greeley Public Library, City Complex Building, Greeley, CO 80631.

Dated at Rockville, Maryland, this 17th day of November, 1993.

For the Nuclear Regulatory Commission.

John H. Austin,

Chief, Decommissioning and Regulatory Issues Branch, Division of Low-Level Waste Management and Decommissioning, Office of Nuclear Material Safety and Safeguards.

[FR Doc. 93–28747 Filed 11–22–93; 8:45 am]

BILLING CODE 7590–01–M

Draft Regulatory Guides; Extension of Comment Period

On October 1, 1993, (58 FR 51392) the NRC issued for public comment drafts of two new guides planned for its Regulatory Guide Series. The draft guides are temporarily identified as DG–1023, "Evaluation of Reactor Pressure Vessels With Charpy Upper-Shelf Energy Less Than 50 Ft–Lb," and DG–1025, "Calculational and Dosimetry Methods for Determining Pressure Vessel Fluence." The draft guides are intended for Division 1, "Power Reactors." DG–1023 is being developed to provide guidance on methods acceptable to the NRC staff for evaluating the reactor pressure vessel when the Charpy upper-shelf falls below the 50 Ft-Lb limit specified in NRC's regulations. DG–1025 is being developed to describe methods and assumptions acceptable to the NRC staff for determining the reactor pressure vessel neutron fluence. Comments for these proposed guides were requested to be received by December 17, 1993. The Commission has received a request to extend the comment period based on the fact that the NRC staff is holding a meeting on Thursday, December 9, 1993, to make presentations on the content of the two guides and to answer questions to clarify positions taken by the staff in those draft guides. Consequently, insufficient time is left to develop comments and to adequately coordinate comments with other individuals and organizations.

The NRC finds it reasonable to extend the public comment period to January 31, 1994, in order to allow all interested person adequate time after the NRC staff presentations to develop and submit comments.

Public comments are being solicited on the guides. Comments should be accompanied by supporting data. Written comments may be submitted to the Rules Review and Directives Branch, Division of Freedom of Information and Publications Services, Office of Administration, U.S. Nuclear Regulatory Commission, Washington, DC 20555. Copies of the comments received may be examined at the NRC Public Document Room, 2120 L Street NW., Washington, DC.

Although a time limit is given for comments on these draft guides, comments and suggestions in connection with items for inclusion in guides currently being developed or improvements in all published guides are encouraged at any time.

Regulatory guides are available for inspection at the Commission's Public Document Room 2120 L Street NW., Washington, DC. Requests for single copies of draft guides (which may be reproduced) or for placement on all automatic distribution lists for single copies of future draft guides in specific divisions should be made in writing to the U.S. Nuclear Regulatory Commission, Washington, DC 20555, Attention: Distribution and Mail Services Section. Telephone requests can not be accommodated. Regulatory guides are not copyrighted, and Commission approval is not required to reproduce them.

Dated at Rockville, Maryland, this 16th day of November 1993.

For the Nuclear Regulatory Commission.

Lawrence C. Shao,

Director, Division of Engineering, Office of Nuclear Regulatory Research.

[FR Doc. 93–28742 Filed 11–22–93; 8:45 am]

BILLING CODE 7590–01–M

[Docket No. 030–30485; License No. 37–28179–01 EA 93–284]

Indiana Regional Cancer Center, Indiana, PA; Order Modifying and Suspending License (Effective Immediately) and Demand for Information

I

Indiana Regional Cancer Center (Licensee) is the holder of Byproduct License No. 37–28179–01 issued by the Nuclear Regulatory Commission (NRC or Commission) pursuant to 10 CFR parts 30 and 35. The license authorizes the licensee to use a strontium-90 source for the treatment of superficial eye conditions. The license, originally issued on April 25, 1988, was due to expire on April 30, 1993, but has remained in effect, pursuant to 10 CFR 30.37(b), based on a timely request for renewal that was received by the NRC on April 5, 1993.

II

On November 11, 1993, the NRC performed an inspection at the facility in Indiana, Pennsylvania. During the inspection, the NRC found that the licensee had used its strontium-90 source to perform treatments of two patients for skin lesions on several occasions between September and November 1993, even though the license does not authorize the use of the strontium-90 for any purpose other than the treatment of superficial eye conditions. The use of the strontium-90 source for treatments of skin lesions is not authorized by the license, and constitutes a violation of the license.

During the inspection, the inspectors asked Dr. James Bauer (Dr. Bauer), the Radiation Safety Officer and only authorized user listed on the license, about the treatment modalities for which the source was used. Dr. Bauer stated that the source had been used for the treatment of pterygium, an eye condition. When the inspectors asked Dr. Bauer whether the source had ever been used for any other modality, Dr. Bauer again replied that the source had been used to treat pterygium. The inspectors then requested records of the last six patients who received treatment with the strontium-90 source. The records provided reflected only eye treatments. Subsequently, the inspectors performed a review of the patient treatment log maintained by Dr. Bauer's secretary, as well as a review of records of additional patient treatments. The NRC learned that the records initially provided were not for the last six patients treated, and that the strontium-90 source had been used for the treatment of superficial lesions of the skin, including a treatment on the day of the inspection that occurred before the inspection took place.

Dr. Bauer's failure to inform the inspectors that he had used the strontium-90 source to treat lesions of the skin, when specifically asked if the source was used for any purpose other than superficial eye treatments, constitutes a violation of the requirements set forth in 10 CFR 30.9 in that the licensee failed to provide complete and accurate information to the NRC. In light of the use of the strontium-90 source for treatment of skin lesions the day of the inspection, Dr. Bauer's communications also appear to constitute a violation of 10 CFR 30.10 in that he appears to have deliberately provided to NRC information that he knew to be incomplete or inaccurate in some material respect.

Previously, Dr. Bauer was involved in an incident in November 1992 at Indiana Regional Cancer Center as the supervisor of a treatment with a High Dose Rate Afterloader that resulted in a patient's being exposed to significant levels of radiation, and numerous other members of the general public were exposed to unnecessary radiation. In that event, he did not cause an adequate survey to be made which could have prevented the exposures.

III

Based on the above, the NRC has serious concerns regarding Dr. Bauer's and the Licensee's conduct of NRC-licensed activities at the Indiana Regional Cancer Center. Specifically, the NRC is concerned: (1) About Dr. Bauer's performance of activities with the strontium-90 source that were not

authorized by the license; (2) with Dr. Bauer's failure to provide complete and accurate information to the inspectors when questioned by the inspectors during the November 11, 1993 inspection; and (3) that a November 1992 event at the Indiana Regional Cancer Center involved a significant misadministration to a patient at the facility, as well as unnecessary radiation exposure to members of the general public, which occurred during or as a result of treatment supervised by Dr. Bauer in which Dr. Bauer failed to cause an adequate survey to be made.

Consequently, I lack the requisite reasonable assurance that information provided to the NRC by Dr. Bauer, the current Radiation Safety Officer and only authorized user listed on the license, will be complete and accurate in all material respects, that the Licensee's current operations can be conducted under License No. 37–28179–01 in compliance with the Commission's requirements, and that the health and safety of the public will be protected. I find that Dr. Bauer is either unable or unwilling to assure that Commission requirements are being and will be followed. Accordingly, the public health, safety and interest require that License No. 37–28179–01 be suspended pending further Order of the Commission and that the license be modified to remove Dr. Bauer from activities under this license. Therefore, the NRC is issuing this Order modifying and suspending License No. 37–28179–01, effective immediately. Furthermore, pursuant to 10 CFR 2.202, I find that the significance of the violations and conduct described above is such that the public health, safety, and interest require that this Order be immediately effective.

Accordingly, pursuant to sections 81, 161b, 161i, 182 and 186 of the Atomic Energy Act of 1954, as amended, and the Commission's regulations in 10 CFR 2.202 and 10 CFR parts 30 and 35, it is hereby ordered, effective immediately, that License No. 37–28179–01 is modified and suspended pending further order as follows:

1. The license is modified to prohibit Dr. Bauer from engaging in activities under the license;

2. The Licensee shall not receive any licensed material; and

3. The Licensee shall cease and desist from any use of byproduct material in its possession and shall immediately place all such material in locked storage.

The Regional Administrator, Region I, may, in writing, relax or rescind this order upon demonstration by the Licensee of good cause.

V

In accordance with 10 CFR 2.202, the Licensee must, and any other person, including Dr. Bauer, adversely affected by this Order may, submit an answer to this Order, and may request a hearing on this Order, within 20 days of the date of this Order. The answer may consent to this Order. Unless the answer consents to this Order, the answer shall, in writing and under oath or affirmation, specifically admit or deny each allegation or charge made in this order and set forth the matters of fact and law on which the Licensee or other person adversely affected relies and the reasons as to why the Order should not have been issued. Any answer or request for a hearing shall be submitted to the Secretary, U.S. Nuclear Regulatory Commission, ATTN: Chief, Docketing and Service Section, Washington, DC 20555. Copies of the hearing request also should be sent to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, Washington, DC 20555, to the Assistant General Counsel for Hearings and Enforcement at the same address, to the Regional Administrator, NRC Region 475 Allendale Road, King of Prussia, Pennsylvania, 19406, and to the Licensee if the hearing request is by a person other than the Licensee. If a person other than the Licensee requests a hearing, that person shall set forth with particularity the manner in which his interest is adversely affected by this Order and shall address the criteria set forth in 10 CFR 2.714(d).

If a hearing is requested by the Licensee or a person whose interest is adversely affected, the Commission will issue an Order designating the time and place of any hearing. If a hearing is held, the issue to be considered at such hearing shall be whether this Order should be sustained.

Pursuant to 10 CFR 2.202 (c)(2)(i), (57 FR 20194, May 12, 1992), the Licensee, or any other person adversely affected by this Order, may, in addition to demanding a hearing, at the time the answer is filed or sooner, move the presiding officer to set aside the immediate effectiveness of the Order on the ground that the Order, including the need for immediate effectiveness, is not based on adequate evidence but on mere suspicion, unfounded allegations, or error.

In the absence of any request for hearing, the provisions specified in section V above shall be final 20 days from the date of this Order without further order or proceedings. An answer or a request for hearing shall not stay the immediate effectiveness of this order.

VI

Demand for Information

In addition, pursuant to sections 161c, 161o, 182 and 186 of the Atomic Energy Act of 1954, as amended, and the Commission's regulations in 10 CFR 2.204 and 10 CFR 30.32(b), in order for the Commission to determine whether the license should be modified or revoked, or other enforcement action taken to ensure compliance with NRC regulatory requirements, the Licensee is required to submit to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, Washington, DC 20555, within 30 days of the date of this Demand for Information, the following information, in writing and under oath or affirmation:

State why, in light of the facts set forth in the above Order, the NRC should not revoke the NRC license; and if such an Order should not be issued why the NRC should have confidence that the Licensee will comply with all Commission requirements.

Dated at Rockville, Maryland, this 16th day of November 1993.

For the Nuclear Regulatory Commission.

James Lieberman,

Director, Office of Enforcement.

[FR Doc. 93–28743 Filed 11–22–93; 8:45 am]

BILLING CODE 7590–01–M

RESOLUTION TRUST CORPORATION

Amended Statement of Policy on Contracting With Firms That Are Parties to Lawsuits With the RTC/FDIC

AGENCY: Resolution Trust Corporation.

ACTION: Amended statement of policy.

SUMMARY: In July of 1992, 57 FR 32839 (July 23, 1992) the Resolution Trust Corporation (RTC) adopted a statement of policy setting forth the factors which it would consider in determining whether the RTC would do business with a firm that was being sued by it, the Federal Deposit Insurance Corporation (FDIC) or the Federal Savings and Loan Insurance Corporation (FSLIC). Under this policy statement, as a general matter the RTC would not do business with entities which were defendants in these actions. In making this determination, however, the RTC could consider a number of factors including, but not limited to: the number of lawsuits, the total amount claimed, the number of individuals or offices named and the type of misconduct alleged.

By decision of the RTC's Executive Committee on November 10, 1993, it

was determined that this policy should be amended. The effect of this amendment is to permit the RTC to apply these same factors to determine whether an entity can do business with the RTC where the RTC has authorized its counsel to sue this same entity, but the proposed litigation has not yet been filed.

DATES: This amendment is effective November 10, 1993.

FOR FURTHER INFORMATION CONTACT: Martin Blumenthal, Contractor Ethics Program Manager, Office of Ethics, (202) 416–2029 or Deborah M. House, Contractor Ethics Supervisor, Office of Ethics (202) 416–2135.

SUPPLEMENTARY INFORMATION: Generally, the RTC does not do business with entities that are being sued by it, the FDIC or FSLIC. The factors which are considered by the RTC's Office of Ethics in determining whether the RTC will do business with a firm, despite existing litigation, were set forth in the Statement of Policy on Contracting with Firms that are Parties to Lawsuits with RTC/FDIC (Litigation Policy), published at 57 FR 32839 (July 23, 1992). The regulatory bases underlying this Policy are that: (1) Entities which have been sued by the RTC may fail to meet the minimum standards of fitness and integrity required of an RTC contractor under 12 CFR Part 1606; and (2) the existence of such litigation may establish organizational conflicts of interest, as defined at 12 CFR 1606.2(j)(2), which create a situation where it is not in best interests of the RTC to contract with the entity which is the subject of the litigation.

To date, the Litigation Policy has been applied to contracting entities by the RTC's Office of Ethics only after a lawsuit has actually been filed. Its application is based on an analysis of the allegations made by the RTC, FDIC or FSLIC in the complaint initiating the litigation. For purposes of this analysis, the allegations contained in the complaint are assumed to be true.

It should be recognized that the final determination by the RTC to file a lawsuit against an entity is a lengthy and complicated internal procedure. The threshold undertaking in this process is a thorough analysis of the facts underlying the potential lawsuit by the RTC and its counsel. It is only after this and other analyses have been completed that authority to file the lawsuit is sought from the RTC's Executive Committee or its delegates. Once authority to sue is granted, the underlying facts upon which the original analysis was based are simply put in the form of a complaint and filed in a court of appropriate jurisdiction.

Accordingly, the RTC's analysis which would support a determination that an entity does not meet the minimum standards of fitness and integrity required of an RTC contractor or that an organizational conflict of interest exists which is an impediment to the RTC's contracting with an entity, is completed much in advance of an actual filing of a complaint. Therefore, it is not necessary for the Office of Ethics to delay action against the contractor until such time as a complaint is filed, provided, however, that the contractor is first given full notice of the factual bases for the proposed determination and an opportunity to respond.

It should be noted that the basis for the vast majority of the lawsuits brought by the RTC is that the entities against which they are filed have contributed to the creation of the savings and loans crisis. The RTC's authorizing legislation, the Financial Institutions, Reform, Recovery and Enforcement Act of 1989, mandates that the RTC decline to do business with entities which contributed to the savings and loan crisis. Therefore, it is consistent with this mandate that the RTC take action at the first possible moment to determine whether these entities should be barred from contracting with the RTC so that they may not benefit further from their own wrongdoing.

By order of the Executive Committee.

Dated at Washington, DC, this 10th day of November, 1993.

Resolution Trust Corporation.

John M. Buckley,

Secretary.

[FR Doc. 93–28707 Filed 11–22–93; 8:45 am]

BILLING CODE 6714–01–M

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–33199; File No. SR–CBOE–93–46]

Self-Regulatory Organizations; Filing of Proposed Rule Change by the Chicago Board Options Exchange, Inc. Relating to FLEX Options on the Nasdaq 100 Index

November 15, 1993.

Pursuant to section 19(b)(1) of the Securities Exchange Act of 1934 ("Act"), 15 U.S.C. 78s(b)(1), notice is hereby given that on October 20, 1993, the Chicago Board Options Exchange, Inc. ("CBOE" or "Exchange") filed with the Securities and Exchange Commission ("Commission") the proposed rule change as described in Items I, II, and III below, which Items have been prepared by the CBOE. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The CBOE proposes to amend its rules to provide for the listing and trading of Flexible Exchange Options ("FLEX Options") on the Nasdaq 100 Index ("NDX Index").[1] The text of the proposed rule change is available at the Office of the Secretary, the CBOE, and at the Commission.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the CBOE included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The CBOE has prepared summaries, set forth in sections (A), (B), and (C) below, of the most significant aspects of such statements.

(A) Self-Regulatory Organization's Statement of the Purpose of, and the Statutory Basis for, the Proposed Rule Change

The purpose of the proposed rule change is to enable the CBOE to expand the FLEX Option program to include FLEX Options on the NDX index. Currently, FLEX Options can be listed and traded only on the S&P 100, the S&P 500, and the Russell 2000 indices. The NDX Index is a capitalization-weighted index composed of the stocks of one hundred of the largest non-financial U.S. issuers whose securities are traded on the Nasdaq National Market. The NDX Index is calculated and maintained by the Nasdaq Stock Market, Inc. ("Nasdaq"), a subsidiary of the National Association of Securities Dealers, Inc. ("NASD").

The proposed rule change includes an amendment to the FLEX Option

[1] On September 22, 1993 and October 27, 1993 (Amendment No. 1), the CBOE submitted a rule change proposal with the Commission (File No. SR–CBOE–93–42) that would provide for the listing and trading of options, including both full-value and reduced-value long-term options series ("LEAPS"), on the NDX Index. That filed proposal, which includes certain background information respecting the makeup and weighting of the NDX Index, and the calculation formula used to derive the Index values, is currently pending Commission review.

position limits. This change would apply the same limits to positions in NDX index options that exist for positions in options on the other indices in the FLEX program. No aggregation provisions are included in this filing for P.M.-settled FLEX Options and "comparable" QIX options, since the CBOE does not anticipate listing and trading QIX options on the NDX Index. If the CBOE determines to list such QIX options in the future, it will amend Rule 24A.7 at that time.

The Exchange believes that the proposed rule change is consistent with section 6(b) of the Act, in general, and furthers the objectives of section 6(b)(5) in particular, in that it is designed to include FLEX Options on the NDX Index in the CBOE's existing FLEX Options program in a manner that promotes just and equitable principles of trade and protects investors and the public interest.

(B) Self-Regulatory Organization's Statement on Burden on Competition

The CBOE does not believe that the proposed rule change will impose any inappropriate burden on competition.

(C) Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants or Others

No written comments were solicited or received with respect to the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Within 35 days of the date of publication of this notice in the **Federal Register** or within such longer period (i) as the Commission may designate up to 90 days of such date if it finds such longer period to be appropriate and publishes its reasons for so finding or (ii) as to which the self-regulatory organization consents, the Commission will:

(A) By order approve such proposed rule change, or

(B) Institute proceedings to determine whether the proposed rule change should be disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing. Persons making written submissions should file six copies thereof with the Secretary, Securities and Exchange Commission, 450 Fifth Street, NW., Washington, DC 20549. Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for inspection and copying in the Commission's Public Reference Section, 450 Fifth Street, NW., Washington, DC. Copies of such filing will also be available for inspection and copying at the principal office of the CBOE. All submissions should refer to File No. SR–CBOE–93–46 and should be submitted by December 14, 1993.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.[2]

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. 93–28674 Filed 11–22–93; 8:45 am]

BILLING CODE 8010–01–M

Self-Regulatory Organizations; Applications for Unlisted Trading Privileges; Notice and Opportunity for Hearing; Boston Stock Exchange, Inc.

November 17, 1993.

The above named national securities exchange has filed applications with the Securities and Exchange Commission ("Commission") pursuant to section 12(f)(1)(B) of the Securities Exchange Act of 1934 and Rule 12f–1 thereunder for unlisted trading privileges in the following securities:

Intelcom Group, Inc.
Common Stock, $.01 Par Value (File No. 7–11536)
Promus Companies, Inc.
Common Stock, $1.50 Par Value (File No. 7–11537)
Shanghai Petrochemical, Inc.
Common Stock, $1.00 Par Value (File No. 7–11538)

These securities are listed and registered on one or more other national securities exchange and are reported in the consolidated transaction reporting system.

Interested persons are invited to submit, on or before December 9, 1993, written data, views and arguments concerning the above-referenced application. Persons desiring to make written comments should file three copies thereof with the Secretary of the Securities and Exchange Commission, 450 5th Street NW., Washington, DC 20549. Following this opportunity for hearing, the Commission will approve the application if it finds, based upon all the information available to it, that the extensions of unlisted trading privileges pursuant to such applications are consistent with the maintenance of fair and orderly markets and the protection of investors.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.

Jonathan G. Katz,

Secretary.

[FR Doc. 93–28673 Filed 11–22–93; 8:45 am]

BILLING CODE 8010–01–M

[2] 17 CFR 200.30–3(a)(12) (1993).

Self-Regulatory Organization; Applications for Unlisted Trading Privileges; Opportunity for Hearing; Chicago Stock Exchange, Incorporated

November 17, 1993.

The above named national securities exchange has filed applications with the Securities and Exchange Commission ("Commission") pursuant to section 12(f)(1)(B) of the Securities Exchange Act of 1934 and rule 12f–1 thereunder for unlisted trading privileges in the following securities:

CBL & Associates Properties, Inc.
Common Stock, $.01 Par Value (File No. 7–11522)
Elan Corporation
Warrants (1.5 Amer. Dep. Shares (each representing one Ord. Shares of ELN) (File No. 7–11523)
Horizon Outlet Centers, Inc.
Common Stock, $.01 Par Value (File No. 7–11524)
Incyte Pharmaceutical, Inc.
Common Stock, $.001 Par Value (File No. 7–11525)
Helionetics, Incorporated
Common Stock, No Par Value (File No. 7–11526)
Avalon Properties, Inc.
Common Stock, $.01 Par Value (File No. 7–11527)
Golden Star Resources Ltd.
Common Stock, $.01 Par Value (File No. 7–11528)
Grupo Tribasa S.A. de C.V.
Amer. Dep. Shares (each representing two shares of Common Stock, No Par Value (File No. 7–11529)
Louis Dreyfus Natural Gas Corp.
Common Stock, $.01 Par Value (File No. 7–11530)
Newfield Exploration Co.
Common Stock, $.01 Par Value (File No. 7–11531)
Vesta Insurance Group, Inc.
Common Stock, $.01 Par Value (File No. 7–11532)
Voyageur Minnesota Municipal Income Fund III, Inc.
Common Stock, $.01 Par Value (File No. 7–11533)
Enersis S.A.
Amer. Dep. Shares (each representing 50 Shares of Common Stock, No Par Value (File No. 7–11534)
Tri-Lite, Inc.

Common Stock, No Par Value (File No. 7–11535)

These securities are listed and registered on one or more other national securities exchange and are reported in the consolidated transaction reporting system.

Interested persons are invited to submit on or before December 9, 1993, written data, views and arguments concerning the above-referenced application. Persons desiring to make written comments should file three copies thereof with the Secretary of the Securities and Exchange Commission, 450 Fifth Street, NW., Washington, DC 20549. Following this opportunity for hearing, the Commission will approve the application if it finds, based upon all the information available to it, that the extensions of unlisted trading privileges pursuant to such application is consistent with the maintenance of fair and orderly markets and the protection of investors.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.

Jonathan G. Katz,

Secretary.

[FR Doc. 93–28667 Filed 11–22–93; 8:45 am]

BILLING CODE 8010–01–M

Self-Regulatory Organizations; Applications for Unlisted Trading Privileges; Opportunity for Hearing; Philadelphia Stock Exchange, Incorporated

November 17, 1993.

The above named national securities exchange has filed applications with the Securities and Exchange Commission ("Commission") pursuant to section 12(f)(1)(B) of the Securities Exchange Act of 1994 and rule 12f–1 thereunder for unlisted trading privileges in the following securities:

Harte Hanks Communications, Inc.
Common Stock, $1.00 Par Value (File No. 7–11497)

Wellsford Residential Property Trust
Series A Cum. Conv. Pfd. Shares of Beneficial Interest $.01 Par Value (File No. 7–11498)

Kimco Realty Corporation
Dep. Shares Each Representing 1.10th of a share 7/75 Cum. Redeemable Pfd Stock $1.00 (File No. 7–11499)

National Intergroup Inc.
$4.20 Cum. Exchangeable Series A Pfd Stock (File No. 7–11500)

ACM Managed Dollar Income Fund, Inc.
Common Stock, $.01 Par Value (File No. 7–11501)

Preferred Income Opportunity Fund, Inc.
Common Stock, $.01 Par Value (File No. 7–11502)

Van Kampen Merritt Advantage Municipal Trust
Common Stock, $.01 Par Value (File No. 7–11503)

Bradley Real Estate Trust
Common Stock, $0.01 Par Value (File No. 7–11504)

MGI Properties
Common Stock, $.01 Par Value (File No. 11505)

Patriot Global Dividend Fund
Common Stock, $.01 Par Value (File No. 7–11506)

Incyte Pharmaceutical, Inc.
Common Stock, $.001 Par Value (File No. 7–11507)

Alabama Power Company
6.80 Class Pfd Stock Cum., $1 Par Value (File No. 7–11508)

Midland Bank Plc
American Depositary Shares Series A (File No. 7–11509)

Corpus Chrisit Bancshares, Inc.
Common Stock, $5.00 Par Value (File No. 7–11510)

Vesta Insurance Group, Inc.
Common Stock, $.01 Par Value (File No. 7–11511)

Avalon Properties, Inc.
Common Stock, $.01 Par Value No. (File No. 7–11512)

Nuveen Insured New York Premium Income Municipal Fund
Common Stock, $.01 Par Value (File No. 7–11513)

Louis Dreyfus Natural Gas Corp.
Common Stock, $.01 Par Value (File No. 7–11514)

Horizon Outlet Centers, Inc.
Common Stock, $.01 Par Value (File No. 7–11515)

Tri-Lite, Inc.
Common Stock, No Par Value (File No. 7–11516)

Voyageur Minnesota Municipal Income Fund III, Inc.
Common Stock, $.01 Par Value (File No. 7–11517)

Paul Revere Corporation
Common Stock, $.01 Par Value (File No. 7–11518)

Enersis S.A.
American Depositary Shares 50 Shares of Common Stock, No Par Value (File No. 7–11519)

Smith Barney High Income Opportunity Fund, Inc.
Common Stock, $0.001 Par Value (File No. 7–11520)

MuiYield Arizona Fund II, Inc.
Common Stock, $.01 Par Value (File No. 7–11521)

These securities are listed and registered on one or more other national securities exchange and is reported in the consolidated transaction reporting system.

Interested persons are invited to submit on or before December 9, 1993, written data, views and arguments concerning the above-referenced applications. Persons desiring to make written comments should file three copies thereof with the Secretary of the Securities and Exchange Commission, 450 5th Street, NW., Washington, DC 20549. Following this opportunity for hearing, the Commission will approve the application if it finds, based upon all the information available to it, that the extensions of unlisted trading privileges pursuant to such applications are consistent with the maintenance of fair and orderly markets and the protection of investors.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.

Jonathan G. Katz,

Secretary.

[FR Doc. 93–28666 Filed 11–22–93; 8:45 am]

BILLING CODE 8010–01–M

[Rel. No. IC–19877; 812–8532]

Liberty Financial Trust, et al.; Application for Exemption

November 16, 1993.

AGENCY: Securities and Exchange Commission (the "SEC" or the "Commission").

ACTION: Notice of application for exemption under the Investment Accompany Act of 1940 (the "Act").

APPLICANTS: Liberty Financial Trust, Liberty Investment Services, Inc. ("Liberty Services"), Liberty Securities Corporation ("Liberty Securities"), and Stein Roe & Farnham Incorporated ("Stein Roe").

RELEVANT ACT SECTIONS: Order requested under section 6(c) of the Act for an exemption from sections 2(a)(32), 2(a)(35), 18(f), 18(g), 18(i), 22(c) and 22(d) of the Act and rule 22c–1 thereunder.

SUMMARY OF APPLICATION: Applicants seek an order (i) to permit certain investment companies to issue multiple classes of shares representing interests in the same portfolio of securities, and (ii) to assess and, under certain circumstances, waive a contingent deferred sales charge ("CDSC") on redemptions of shares.

FILING DATE: The application was filed on August 10, 1993. Applicants have agreed to file an additional amendment, the substance of which is incorporated herein, during the notice period.

HEARING OR NOTIFICATION OF HEARING: An order granting the application will be issued unless the SEC orders a hearing. Interested persons may request a hearing by writing to the SEC's Secretary and serving applicants with a copy of the request, personally or by mail. Hearing requests should be

received by the SEC by 5:30 p.m., on December 13, 1993, and should be accompanied by proof of service on the applicants in the form of an affidavit or, for lawyers, a certificate of service. Hearing requests should state the nature of the writer's interest, the reason for the request, and the issues contested. Persons who wish to be notified of a hearing may request notification by writing to the SEC's Secretary.

ADDRESSES: Secretary, SEC, 450 5th Street, NW., Washington, DC 20549; Applicants; 600 Atlantic Avenue, Boston, Massachusetts 02210.

FOR FURTHER INFORMATION CONTACT: Elaine M. Boggs, Staff Attorney, at (202) 272–3026 or Robert A. Robertson, Branch Chief, at (202) 272–3030 (Division of Investment Management, Office of Investment Company Regulation).

SUPPLEMENTARY INFORMATION: The following is a summary of the application. The complete application is available for a fee at the SEC's Public Reference Branch.

Applicants' Representations

1. Liberty Financial Trust is an open-end management investment company registered under the Act that currently has five series, or portfolios (the "Liberty Financial Funds"). Stein Roe, an indirect wholly-owned subsidiary of Liberty Financial Companies, Inc. ("LFC"), and an affiliate of Liberty Securities and Liberty Services, is the investment manager of four of the series and of the separate registered investment company in which the fifth series invests substantially all of its assets. Liberty Services provides administrative services to the Liberty Financial Trust and the Liberty Financial Funds. Liberty Securities is the principal underwriter of the Liberty Financial Funds.

2. Applicants request that relief extend to all existing and future series of Liberty Financial Trust and any management investment company (including all series thereof) for which in the future Liberty Securities or any majority-owned subsidiary of LFC is the principal underwriter (collectively, with the Liberty Financial Funds, the "Funds").

A. The Multiple Class Distribution System

1. Applicants proposed to establish a multiple distribution system enabling each Fund to offer investors the option of purchasing shares (a) subject to a front-end sales load and, in most cases, a distribution and/or service fee pursuant to a rule 12b–1 plan ("Class A Shares"), (b) without a front-end sales load, but subject to a CDSC, a distribution fee and/or a service fee pursuant to a rule 12b–1 plan, and a conversion feature as described below ("Class B Shares"), or (c) without a front-end sales load, but subject to a CDSC (which is lower than, and for a shorter period of time than, the CDSC for the Class B shares), a distribution fee and/or service fee pursuant to a rule 12b–1 plan, but no conversion feature ("Class C Shares"). Any distribution arrangement of a Fund, including rule 12b–1 fees and front-end and deferred sales loads, will comply with Article III, section 26, of the Rules of Fair Practice of the National Association of Securities Dealers, Inc.

2. Applicants also seek the authority to create one or more additional classes of shares in the future, the terms of which may differ from the Class A, Class B, and Class C shares only in the following respects: (a) Any such class may bear different or no service and distribution fees and any other costs relating to implementing or amending the rule 12b–1 plan for such class, (b) any such class may bear any incremental difference in shareholder servicing fees, (c) any such class may bear different class designations, (d) any such class will have exclusive voting rights with respect to any rule 12b–1 plan adopted exclusively with respect to such class except as provided in condition 15 below, (e) any such class may bear any other incremental expenses subsequently identified that should be properly allocated to such class which shall be approved by the SEC pursuant to an amended order, (f) any such class may have different conversion features, (g) any such class may have different exchange privileges, (h) any such class may be sold under different sales arrangements, including selling only to a particular type of investor, and (i) any such class may bear different printing and postage expenses relating to preparing and distributing materials such as shareholder reports, prospectuses, and proxy statements ("Class Expenses") relating to that class.

3. After a shareholder's Class B shares remain outstanding for a specified period of time (not to exceed eight years), they will automatically convert to Class A shares of the same Fund at the relative net asset values of each of the classes and will thereafter be subject to the lower fee under the Class A rule 12b–1 plan. In addition, any other class may provide that its shares (the "Purchase Class") will, after a period of time, automatically convert into another class (the "Target Class").

B. The CDSC

1. Applicants also request relief to permit the Funds to assess a CDSC on certain redemptions of Fund shares, and to permit the Funds to waive or reduce the CDSC with respect to certain types of redemptions. The amount of the CDSC to be imposed will depend on the amount of time since the investor purchased the shares being redeemed, as set forth in each Fund's prospectus. The CDSC schedule for any class having a CDSC will comply, to the extent applicable, with the requirements of section 26(d) of the Rules of Fair Practice of the NASD.

2. No CDSC would be imposed on an amount which represents an increase in the value of the shareholder's account resulting from capital appreciation above the amount paid for the CDSC shares purchased. In determining the applicability and rate of any CDSC, it would be assumed that a redemption is made first of shares not subject to the CDSC, including shares representing capital appreciation and shares representing the automatic reinvestment of dividends, and then of other shares held by the shareholder for the longest period of time.

3. The Funds also are requesting the ability to waive or reduce the CDSC in the following instances: (a) On redemptions following the death, disability, or financial hardship of a shareholder; (b) redemptions in connection with (i) distributions to participants or beneficiaries of plans qualified under sections 401(a) or 401(k) of the Internal Revenue Code (the "Code"); custodial accounts, individual retirement accounts, or deferred compensation plans under the Code; and other employee benefit or retirement plans, (ii) return of excess contributions to these plans, and (iii) the enactment or promulgation of any law or regulation pursuant to which continuation of the investment in the Funds would be improper; (c) in connection with redemptions of shares made pursuant to a shareholder's participation in any systematic withdrawal plan adopted by a Fund; (d) redemptions pursuant to the Funds' right to liquidate an account; (e) redemptions of shares acquired as a result of investment of distributions from shares of a class of one Fund into shares of the same class of another Fund; and (f) in connection with shares sold to certain individuals or groups or in certain situations, as described below: (i) Current and retired trustees and officers of the Funds, and current and retired directors, advisory board members, officers, employees and sales

representatives of Liberty Mutual Insurance Company and its affiliates, (ii) trust companies and bank trust departments with respect to funds as to which they exercise investment authority, (iii) clients of Stein Roe and prototype retirement plans sponsored by it and its affiliates, (iv) pension, profit-sharing or other qualified employee benefit plans covering 50 or more employees, (v) officers, directors and employees of banks and savings institutions with which Liberty Securities or its affiliates have operating or lease arrangements relating to the sale of securities or insurance products by or from the premises of such institutions; and (vi) where the amount invested represents redemption proceeds from a registered open-end management investment company other than a Fund purchased through Liberty Securities or any broker-dealer approved by the Board of Trustees of the Fund, provided that no deferred sales charge is payable with respect to the redemption proceeds.

4. In connection with waiver category (f) (vi) above, applicants will take such steps as may be necessary to determine that the shareholder has not paid a deferred sales load, fee, or other charge in connection with the redemption of shares of the other open-end investment company, including, without limitation, requiring the shareholder to provide a written representation that neither a deferred sales load, fee, nor other charge was imposed upon the redemption, and, in addition, either (a) requiring such shareholder to provide an activity statement reflecting the redemption that supports the shareholder's representation or (b) reviewing a copy of the current prospectus of the other open-end investment company and determining that such company does not impose a deferred sales load, fee, or other charge in connection with the redemption of shares.

Applicants' Legal Analysis

1. Applicants seek relief from sections 18(f)(1), 18(g), and 18(i) to issue multiple classes of shares representing interests in the same portfolio of securities. Applicants believe that by implementing the Multiple Class Distribution System, an investor would be able to choose the sales financing method which best suits the investor's situation. Applicants also believe that the proposed allocation of expenses and voting rights in the manner described above is equitable and would not discriminate against any group of shareholders.

2. The proposed arrangement does not involve borrowings, and does not affect the Funds' existing assets or reserves. Nor will the proposed arrangement increase the speculative character of the shares of a Fund, since all such shares will participate in the Fund's appreciation, income, and expenses in the manner described above.

3. Applicants also seek relief from sections 2(a)(32), 2(a)(35), 22(c), and 22(d) of the Act and rule 22c–1 thereunder to assess and, under certain circumstances, waive a CDSC on redemptions of shares. Applicants believe that the contingent nature of the proposed charge places the purchaser in a better position than if a sales load were imposed at the time of sale, since in the case of the CDSC there is a possibility that the shareholder will have to pay only a reduced sales charge, or no sales charge at all.

Applicant's Conditions

Applicants agree that the order of the Commission granting the requested relief shall be subject to the following conditions:

A. The Multiple Distribution System

1. Each class of shares of a Fund will represent interests in the same portfolio of investments of that Fund, and be identical in all respects, except as set forth below. The only differences among the various classes of shares of the same Fund will relate solely to: (a) The impact of the different distribution and service fee payments associated with any rule 12b–1 plan relating to a particular class of shares and any other costs relating to the implementation of such plan or any amendments thereto (including obtaining shareholder approval of such plan or any amendment thereto) which will be borne solely by shareholders of such class, any incremental shareholder servicing fees attributable solely to a particular class of shares of the Fund, and any other incremental expenses subsequently identified that should be properly allocated to one class which shall be approved by the Commission pursuant to an amended order; (b) the voting rights on matters that pertain to the rule 12b–1 plans, except as provided in condition 15 below; (c) the different exchange privileges of each class of shares; (d) the designation of each class of shares of the Fund; (e) the differences in conversion features of each class of shares; and (f) any differences in Class Expenses of each class of shares.

2. The board of trustees of each Fund, including a majority of the independent trustees, will approve the multiple distribution system for a particular Fund prior to its implementation by such Fund. The minutes of the meetings of the trustees regarding their deliberations with respect to the approvals necessary to implement the multiple distribution system will reflect in detail the reasons for the trustees' determination that the proposed multiple distribution system is in the best interests of both the Fund and its shareholders.

3. On an ongoing basis, the board of trustees of the Funds, pursuant to their fiduciary responsibilities under the Act and otherwise, will monitor each Fund for the existence of any material conflicts between the interests of the various classes of shares. The trustees, including a majority of the independent trustees, shall take such action as is reasonably necessary to eliminate any such conflicts that may develop. Liberty Investment Services, Liberty Securities, and Stein Roe will be responsible for reporting any potential or existing conflicts to the trustees. If a conflict arises, Liberty Investment Services, Liberty Securities, and Stein Roe, at their own cost, will remedy such conflict up to and including establishing a new registered management investment company.

4. The trustees of the Funds will receive quarterly and annual statements concerning distribution and service expenditures complying with paragraph (b)(3)(ii) of rule 12b–1, as amended from time to time. In these statements, only expenditures properly attributable to the sale of a particular class of shares or to the provision of services to holders of such shares will be used to justify any distribution or service fee attributable to such class. Expenditures not related to the sale or service of a particular class or to services provided to holders of such shares will not be presented to the trustees to justify any fee attributable to that class. The statements, including the allocations upon which they are based, will be subject to the review of the independent trustees of the Funds in the exercise of their fiduciary duties.

5. Dividends paid by the Fund with respect to each class of its shares, to the extent any dividends are paid, will be calculated in the same manner, at the same time, on the same day, and will be in the same amount, except that (a) distribution and service fee payments associated with any rule 12b–1 plan relating to a particular class or shares (and any other costs relating to implementing the rule 12b–1 plan for such class or any amendment to such plan including obtaining shareholder approval of the rule 12b–1 plan for such class or any amendment to such plan) will be borne exclusively by that class; (b) any incremental shareholder servicing fees relating to a particular

class will be borne exclusively by that class; (c) Class Expenses relating to a particular class will be borne exclusively by that class; and (d) any other incremental expenses subsequently identified that should be properly allocated to a particular class which shall be approved by the Commission pursuant to an amended order will be borne exclusively by such class.

6. The methodology and procedures for calculating the net asset value and dividends and distributions of the various classes and the proper allocation of expenses between the various classes has been reviewed by an expert (the "Expert") who has rendered a report to applicants, a copy of which has been filed as an exhibit to the application, stating that such methodology and procedures are adequate to ensure that such calculations and allocations will be made in an appropriate manner. On an ongoing basis, the Expert, or an appropriate substitute Expert, will monitor the manner in which the calculations and allocations are being made and, based upon such review, will render at least annually a report to the Fund that the calculations and allocations are being made properly. The reports of the Expert shall be filed as part of the periodic reports filed with the Commission pursuant to sections 30(a) and 30(b)(1) of the Act. The work papers of the Expert with respect to such reports, following request by the Funds (which the Funds agree to make), will be available for inspection by the Commission staff upon the written request to the Fund for such work papers by a senior member of the Division of Investment Management or of a Regional Office of the Commission, limited to the Director, an Associate Director, the Chief Accountant, the Chief Financial Analyst, an Assistant Director, and any Regional Administrators or Associate and Assistant Administrators. The initial report of the Expert is a "Special Purpose" report on the "Design of a System," as defined and described in SAS No. 44 of the AICPA, and the ongoing reports will be "reports on policies and procedures placed in operation and tests of operating effectiveness" as defined and described in SAS No. 70 of the AICPA, as it may be amended from time to time, or in similar auditing standards as may be adopted by the AICPA from time to time.

7. Applicants have adequate facilities in place to ensure implementation of the methodology and procedures for calculating the net asset value and dividends and distributions of the various classes of shares and the proper allocation of expenses among such classes of shares, and this representation has been concurred with by the Expert in the initial report referred to in condition 6 above and will be concurred with by the Expert, or an appropriate substitute Expert, on an ongoing basis at least annually in the ongoing reports referred to in condition 6 above. Applicants agree to take immediate corrective action if the Expert, or appropriate substitute Expert, does not so concur in the ongoing reports.

8. The prospectuses of the Funds will contain a statement to the effect that a salesperson and any other person entitled to receive compensation for selling or servicing Fund shares may receive different compensation with respect to one particular class of shares over another in the Fund.

9. Liberty Securities will adopt compliance standards as to when each class of shares may appropriately be sold to particular investors. Applicants will require their registered representatives and all broker-dealer firms with which they enter into selling agreements regarding the Funds to agree to conform to such standards.

10. The conditions pursuant to which the exemptive order is granted and the duties and responsibilities of the trustees of the Funds with respect to the multiple distribution system will be set forth in guidelines that will be furnished to the trustees as part of the materials setting forth the duties and responsibilities of the trustees.

11. Each Fund will disclose in its prospectus the respective expenses, performance data, distribution agreements, services, fees, sales loads, contingent deferred sales loads, conversion features, and exchange privileges applicable to each class of shares in every prospectus, regardless of whether all classes of shares are offered through each prospectus. The shareholder reports of each Fund will disclose the respective expenses and performance data applicable to each class of shares. The shareholder reports will contain, in the statement of asset and liabilities and statement of operations, information related to the Fund as a whole generally and not on a per class basis. Each Fund's per share data, however, will be prepared on a per class basis with respect to the classes of shares of such Fund. To the extent any advertisement or sales literature describes the expenses or performance data applicable to any class of shares, it will disclose the expenses and/or performance data applicable to all classes of shares. The information provided by applicants for publication in any newspaper or similar listing of the Funds' net asset value and public offering prices will present each class of shares separately.

12. Applicants acknowledge that the grant of the exemptive order requested by the application will not imply Commission approval, authorization, or acquiescence in any particular level of payments that the Funds may make pursuant to their rule 12b–1 distribution in reliance on the exemptive order.

13. Purchase Class shares will convert into Target Class shares on the basis of the relative net asset values of the two classes, without the imposition of any sales load, fee, or other charge. After conversion, the converted shares will be subject to an asset-based sales charge and/or service fee (as those terms are defined in Article III, Section 26 of the NASD's Rules of Fair Practice), if any, that in the aggregate are lower than the asset-based charge and service fee to which they were subject prior to the conversion.

14. The initial determination of the Class Expenses, if any, that will be allocated to a particular class of a Fund and any subsequent changes thereto will be reviewed and approved by a vote of the board of trustees of the Fund, including a majority of the independent trustees. Any person authorized to direct the allocation and disposition of the monies paid or payable by the Fund to meet Class Expenses shall provide to the board of trustees, and the board of trustees shall review, at least quarterly, a written report of the amounts so expended and the purposes for which such expenditures were made.

15. If a Fund implements any amendment to its rule 12b–1 plan (or, if presented to shareholders, adopts or implements any amendment of a non-rule 12b–1 shareholder services plan) that would increase materially the amount that may be borne by the Target Class shares under the plan, existing Purchase Class shares will stop converting into Target Class unless the Purchase Class shareholders, voting separately as a class, approve the proposal. The trustees shall take such action as is necessary to ensure that existing Purchase Class shares are exchanged or converted into a new class of shares ("New Target Class"), identical in all material respects to the Target Class as it existed prior to implementation of the proposal, no later than the date such shares previously were scheduled to convert into Target Class shares. If deemed advisable by the trustees to implement the foregoing, such action may include the exchange of all existing Purchase Class shares for

a new class ("New Purchase Class"), identical to existing Purchase Class shares in all material respects except that New Purchase Class will convert into New Target Class. The New Target Class or the New Purchase Class may be formed without further exemptive relief. Exchanges or conversions described in this condition shall be effected in a manner that the trustees reasonably believe will not be subject to Federal taxation. In accordance with condition 3, any additional cost associated with the creation, exchange, or conversion of New Target Class or New Purchase Class shares shall be borne solely by Liberty Securities, Liberty Services, or Stein Roe. Purchase Class shares sold after the implementation of the proposal may convert into Target Class shares subject to the higher maximum payment, provided that the material features of the Target Class plan and the relationship of such plan to the Purchase Class shares are disclosed in an effective registration statement.

B. The CDSC

1. Applicants will comply with the provisions of proposed rule 6c–10 under the Act (see Investment Company Act Release No. 16619 (Nov. 2, 1988)), as such rule is currently proposed and as it may be reproposed, adopted, or amended.

For the Commission, by the Division of Investment Management, under delegated authority

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. 93–28672 Filed 11–22–93; 8:45 am]

BILLING CODE 8010–01–M

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

Approval of an Amendment to the Noise Compatibility Program; Des Moines International Airport, Des Moines, IA

AGENCY: Federal Aviation Administration, DOT.

ACTION: Notice.

SUMMARY: The Federal Aviation Administration (FAA) announces its findings on the amendment to the approved Noise Compatibility Program submitted by the City of Des Moines under the provisions of title I of the Aviation Safety and Noise Abatement Act of 1979 (Pub. L. 96–193) (hereinafter referred to as the "Act") and 14 CFR part 150. These findings are made in recognition of the description of Federal and nonfederal responsibilities in Senate Report No. 96–52 (1980). On February 1, 1991, the FAA determined that the noise exposure maps submitted by the City of Des Moines under part 150 were in compliance with applicable requirements. On July 30, 1991, the Assistant Administrator for Airports approved the Noise Compatibility Program. All of the recommendations of the program were approved. On September 15, 1993, the Assistant Administrator approved the amendment to the Des Moines International Airport Noise Compatibility Program. All of the recommendations of the amendment were approved. No program elements relating to new or revised flight procedures for noise abatement were proposed by the airport operator.

EFFECTIVE DATE: The effective date of the FAA's approval of the amendment to the Des Moines International Airport Noise Compatibility Program is September 15, 1993.

FOR FURTHER INFORMATION CONTACT: G. Alan Wimpey, Airport Planner (IA), Airports Division, ACE–611C, 601 E. 12th Street Kansas City, Missouri 64106 (Telephone—816–426–4739). Documents reflecting this FAA action may be reviewed at this same location.

SUPPLEMENTARY INFORMATION: This notice announces that the FAA has given its overall approval to an amendment to the approved Noise Compatibility Program for the Des Moines International Airport, effective September 15, 1993.

Under section 104(a) of the Act, an airport operator who has previously submitted Noise Exposure Maps that are found by FAA to be in compliance with the requirements of FAR part 150, promulgated pursuant to title I of the Act, may submit to the FAA a Noise Compatibility Program, or an amendment thereto for FAA approval which sets forth the measures taken or proposed by the airport operator for the reduction of existing noncompatible land uses and prevention of additional noncompatible uses within the area covered by the noise exposure maps. The Act requires such programs to be developed in consultation with interested and affected parties including local communities, governmental agencies, airport users, and FAA personnel.

Each airport noise compatibility program, or amendment thereto, developed in accordance with FAR part 150 is a local program, not a Federal program. The FAA does not substitute its judgment for that of the airport proprietor with respect to what measures should be recommended for action. The FAA's approval or disapproval of FAR part 150 program recommendations is measured according to the standards expressed in part 150 and the Act, and in this case is limited to the following determinations:

a. The amendment to the noise compatibility program was developed in accordance with the provisions and procedures of FAR part 150;

b. Program measures are reasonably consistent with achieving the goals of reducing existing noncompatible land uses around the airport and preventing the introduction of additional noncompatible land uses;

c. Program measures would not create an undue burden on interstate or foreign commerce, unjustly discriminate against types or classes of aeronautical uses, violate the terms of airport grant agreements, or intrude into areas preempted by the Federal Government; and

d. Program measures relating to the use of flight procedures can be implemented within the period covered by the program without derogating safety, adversely affecting the efficient use and management of the navigable airspace and air traffic control systems, or adversely affecting other powers and responsibilities of the Administrator prescribed by law.

Specific limitations with respect to FAA's approval of an airport noise compatibility program or amendment thereto, are delineated in FAR part 150, paragraph 150.5. Approval is not a determination concerning the acceptability of land uses under Federal, state, or local law. Approval does not by itself constitute an FAA implementing action. A request for Federal action or approval to implement specific noise compatibility measures may be required, and an FAA decision on the request may require an environmental assessment of the proposed action. Approval does not constitute a commitment by the FAA to financially assist in the implementation of the amendment nor a determination that all measures covered by the amendment are eligible for grant-in-aid funding from the FAA. Where federal funding is sought, request for project grants must be submitted to the FAA Regional Office in Kansas City, Missouri.

This amendment was submitted subsequent to a determination by FAA that associated noise exposure maps submitted under 14 CFR part 150 for Des Moines International Airport were in compliance with applicable requirements on February 1, 1991. Notice of this determination was published in the **Federal Register** on February 20, 1991. On July 30, 1991, the

FAA approved the Noise Compatibility Program, FAA published its findings in the Federal Register on September 6, 1991.

The amendment contains elements designed for phased implementation by airport management beginning in 1993 to the year 2000. It was requested that the FAA review and approve this material as an amendment to the noise compatibility program as described in section 104(b) of the Act.

The FAA began its review of the proposed amendment to the approved noise compatibility program on April 20, 1993 and was required by a provision in the Act to approve or disapprove the amendment within 180 days (other than the use of new flight procedures for noise control). Failure to approve or disapprove such amendment within the 180-day period shall be deemed to be an approval of such amendment.

The submitted amendment contained two proposed elements for noise mitigation off the airport. The FAA completed its review and determined that the procedural and substantive requirements of the Act and FAR part 150 have been satisfied. The amendment to the approved Noise Compatibility Program, therefore, was approved by the Assistant Administrator effective September 15, 1993.

Outright approval was granted for all of the specific program elements. The approved actions were land use management strategies that included a voluntary Resale Assurance Program for those fixed (non-mobile) residential properties above the 70 DNL noise contour and as an alternative to the Resale Assurance Program, the city will offer a Noise and Aviation Easement Purchase Program for those residential property owners who desire to remain within the 70 DNL noise contour.

These determinations are set forth in detail in a Supplemental Record of Approval endorsed by the Assistant Administrator on September 15, 1993. The Supplemental Record of Approval, as well as other evaluation materials and the documents comprising the submittal, are available for review at the FAA office listed above and at the administrative offices of the Des Moines International Airport.

Issued in Kansas City, Missouri, on November 5, 1993.

George A. Hendon,

Manager, Airports Division.

[FR Doc. 93-28713 Filed 11-22-93; 8:45 am]

BILLING CODE 4910-13-M

Acceptance of Noise Exposure Maps and Request for Review of Noise Compatibility Program for Hilo International Airport, Hilo, HI

AGENCY: Federal Aviation Administration, DOT.

ACTION: Notice.

SUMMARY: The Federal Aviation Administration (FAA) announces its determination that the noise exposure maps submitted by the State of Hawaii, Department of Transportation for the Hilo International Airport under the provisions of title I of the Aviation Safety and Noise Abatement Act of 1979 (Public Law 96-193) and 14 CFR part 150 are in compliance with applicable requirements. The FAA also announces that it is reviewing a proposed noise compatibility program that was submitted for Hilo International Airport under part 150 in conjunction with the noise exposure map, and that this program will be approved or disapproved on or before May 3, 1994.

EFFECTIVE DATE: The effective date of the FAA's determination on the noise exposure maps and of the start of its review of the associated noise compatibility program is November 4, 1993. The public comment period ends December 30, 1993.

FOR FURTHER INFORMATION CONTACT: David J. Welhouse, Airport Engineer/Planner, Honolulu Airports District Office, Federal Aviation Administration, P.O. Box 50244, Honolulu, Hawaii 96850, Telephone: (808) 541-1243. Comments on the proposed noise compatibility program should also be submitted to the above office.

SUPPLEMENTARY INFORMATION: This notice announces that the FAA finds that the noise exposure maps submitted for Hilo International Airport are in compliance with applicable requirements of part 150, effective November 4, 1993. Further, FAA is reviewing a proposed noise compatibility program for that airport which will be approved or disapproved on or before May 3, 1994. This notice also announces the availability of this program for public review and comment.

Under section 103 of title I of the Aviation Safety and Noise Abatement Act of 1979 (hereinafter referred to as "the Act"), an airport operator may submit to the FAA noise exposure maps which meet applicable regulations and which depict noncompatible land uses as of the date of submission of such maps, a description of projected aircraft operations, and the ways in which such operations will affect such maps. The Act requires such maps to be developed in consultation with interested and affected parties in the local community, government agencies, and persons using the airport.

An airport operator who has submitted noise exposure maps that are found by FAA to be in compliance with the requirements of Federal Aviation Regulations (FAR) part 150, promulgated pursuant to title I of the Act, may submit a noise compatibility program for FAA approval which sets forth the measures the operator has taken or proposes for the reduction of existing noncompatible uses and for the prevention of the introduction of additional noncompatible uses.

The State of Hawaii, Department of Transportation, submitted to the FAA on December 28, 1992 noise exposure maps, descriptions and other documentation which were produced during the preparation of the Hilo International Airport Noise Compatibility Study dated December, 1992. It was requested that the FAA review this material as the noise exposure maps, as described in section 103(a)(1) of the Act, and that the noise mitigation measures, to be implemented jointly by the airport and surrounding communities, be approved as a noise compatibility program under section 104(b) of the Act.

The FAA has completed its review of the noise exposure maps and related descriptions submitted by the State of Hawaii, Department of Transportation. The specific maps under consideration are Figures 2-2 and 2-3 in the submission. The FAA has determined that these maps for Hilo International Airport are in compliance with applicable requirements. This determination is effective on November 4, 1993. FAA's determination on an airport operator's noise exposure maps is limited to a finding that the maps were developed in accordance with the procedures contained in appendix A of FAR part 150. Such determination does not constitute approval of the applicant's data, information or plans, or a commitment to approve a noise compatibility program or to fund the implementation of that program.

If questions arise concerning the precise relationship of specific properties to noise exposure contours depicted on a noise exposure map submitted under section 103 of the Act, it should be noted that the FAA is not involved in any way in determining the relative locations of specific properties with regard to the depicted noise contours, or in interpreting the noise exposure maps to resolve questions concerning, for example, which

properties should be covered by the provisions of section 107 of the Act. These functions are inseparable from the ultimate land use control and planning responsibilities of local government. These local responsibilities are not changed in any way under part 150 or through FAA's review of noise exposure maps. Therefore, the responsibility for the detailed overlaying of noise exposure contours onto the map depicting properties on the surface rests exclusively with the airport operator which submitted those maps, or with those public agencies and planning agencies with which consultation is required under section 103 of the Act. The FAA has relied on the certification by the airport operator, under § 150.21 of FAR part 150, that the statutorily required consultation has been accomplished.

The FAA has formally received the noise compatibility program for Hilo International Airport, also effective on November 4, 1993. Preliminary review of the submitted material indicates that it conforms to the requirements for the submittal of noise compatibility programs, but that further review will be necessary prior to approval or disapproval of the program. The formal review period, limited by law to a maximum of 180 days, will be completed on or before May 3, 1994.

The FAA's detailed evaluation will be conducted under the provisions of 14 CFR part 150, § 150.33. The primary considerations in the evaluation process are whether the proposed measures may reduce the level of aviation safety, create an undue burden on interstate or foreign commerce, or be reasonably consistent with obtaining the goal of reducing existing noncompatible land uses and preventing the introduction of additional noncompatible land uses.

Interested persons are invited to comment on the proposed program with specific reference to these factors. All comments, other than those properly addressed to local land use authorities, will be considered by the FAA to the extent practicable. Copies of the noise exposure maps, the FAA's evaluation of the maps, and the proposed noise compatibility program are available for examination at the following locations:

Federal Aviation Administration, 800 Independence Avenue, SW., room 617, Washington, DC 20591

Federal Aviation Administration, Western-Pacific Region, Airports Division, AWP–600, 15000 Aviation Blvd., room 3E24, Hawthorne, California 90261

Federal Aviation Administration, Honolulu Airports District Office, 300 Ala Moana Boulevard, room 7116, Honolulu, Hawaii 96813

State of Hawaii, Department of Transportation, Airports Division, Honolulu International Airport, 400 Rodgers Boulevard, suite 700, Honolulu, Hawaii 96819

State of Hawaii, Department of Transportation, Airports Division, District Office Manager, Hilo International Airport, Hilo, Hawaii 96720.

Questions may be directed to the individual named above under the heading, **FOR FURTHER INFORMATION CONTACT.**

Issued in Hawthorne, California, on November 4, 1993.

Herman C. Bliss,

Manager, Airports Division, AWP–600, Western-Pacific Region.

[FR Doc. 93–28711 Filed 11–22–93; 8:45 am]

BILLING CODE 4910–13–M

Noise Exposure Map Notice, Smyrna Airport, Smyrna, TN

AGENCY: Federal Aviation Administration, DOT.

ACTION: Notice.

SUMMARY: The Federal Aviation Administration (FAA) announces its determination that the updated noise exposure maps submitted by Metropolitan Nashville Airport Authority and Smyrna/Rutherford County Airport Authority for Smyrna Airport under the provisions of title I of the Aviation Safety and Noise Abatement Act of 1979 (Public Law 96–193) and 14 CFR part 150 are in compliance with applicable requirements.

EFFECTIVE DATE: The effective date of the FAA's determination on the noise exposure is November 10, 1993.

FOR FURTHER INFORMATION CONTACT: Federal Aviation Administration, Peggy S. Kelley, Memphis Airports District Office, 2851 Directors Cove, suite 3, Memphis, Tennessee 38131–0301 Telephone: 901–544–3495.

SUPPLEMENTARY INFORMATION: This notice announces that the FAA finds that the updated noise exposure maps submitted for Smyrna Airport are in compliance with applicable requirements of part 150, effective November 10, 1993.

Under section 103 of the Aviation Safety and Noise Abatement Act of 1979 (hereinafter referred to as "the Act"), an airport operator may submit to the FAA noise exposure maps which meet applicable regulations and which depict noncompatible land uses as of the date of submission of such maps, a description of projected aircraft operations, and the ways in which such operations will affect such maps. The Act requires such maps to be developed in consultation with interested and affected parties in the local community, government agencies, and persons using the airport.

An airport operator who has submitted noise exposure maps that are found by FAA to be in compliance with the requirements of Federal Aviation Regulations (FAR) part 150, promulgated pursuant to title I of the Act, may submit a noise compatibility program for FAA approval which sets forth the measures the operator has taken or proposes for the prevention of the introduction of additional noncompatible uses.

The FAA has completed its review of the noise exposure maps and related descriptions submitted by Metropolitan Nashville Airport Authority and Smyrna/Rutherford County Airport Authority. The specific maps submitted for consideration are 1989 Contours With Existing Off-Airport Land Use and 1995 Recommended Noise Abatement Contours With Existing Off-Airport Land Use. The current map (1989) was based on 1989 aircraft operations, which exceeded the 1992 aircraft operations. The FAA has determined that these maps for Smyrna Airport are in compliance with applicable requirements. This determination is effective on November 10, 1993. FAA's determination on an airport operator's noise exposure maps is limited to a finding that the maps were developed in accordance with the procedures contained in appendix A of FAR part 150. Such determination does not constitute approval of the applicant's data, information or plans, or a commitment to approve a noise compatibility program or to fund the implementation of that program.

If questions arise concerning the precise relationship of specific properties to noise exposure contours depicted on a noise exposure map submitted under section 103 of the Act, it should be noted that the FAA is not involved in any way in determining the relative locations of specific properties with regard to the depicted noise contours, or in interpreting the noise exposure maps to resolve questions concerning, for example, which properties should be covered by section 107 of the Act. These functions are inseparable from the ultimate land use control and planning responsibilities of local government. These local responsibilities are not changed in any way under part 150, or through FAA's

review of noise exposure maps. Therefore, the responsibility for the detailed overlaying of noise exposure contours onto the map depicting properties on the surface rests exclusively with the airport operator which submitted those maps, or with those public agencies and planning agencies with which consultation is required under section 103 of the Act. The FAA has relied on the certification by the airport operator, under § 150.21 of FAR part 105, that the statutorily required consultation has been accomplished.

Copies of the noise exposure maps and of the FAA's evaluation of the maps are available for examination at the following locations:

Federal Aviation Administration, 800 Independence Avenue SW., room 617, Washington, DC 20591

Federal Aviation Administration, Airports District Office, 2851 Directors Cove, suite 3, Memphis, Tennessee 38131–0301

Administrative Offices, Smyrna Airport, Smyrna, Tennessee.

Questions may be directed to the individual named above under the heading **FOR FURTHER INFORMATION CONTACT.**

Issued in Memphis, Tennessee, November 10, 1993.

Billy J. Langley,

Manager, Memphis Airports District Office.

[FR Doc. 93–28710 Filed 11–22–93; 8:45 am]

BILLING CODE 4910–13–M

Aviation Rulemaking Advisory Committee; Parts Approval Action Team—Phase 3 Working Group

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of establishment of Parts Approval Action Team—Phase 3 Working Group.

SUMMARY: Notice is given of the establishment of the Parts Approval Action Team—Phase 3 Working Group of the Aviation Rulemaking Advisory Committee (ARAC). This notice informs the public of the activities of the ARAC on air carrier/general aviation maintenance issues.

FOR FURTHER INFORMATION CONTACT: Mr. Frederick J. Leonelli, Assistant Executive Director for Air Carrier/General Aviation Maintenance Issues, Aviation Rulemaking Advisory Committee, Flight Standards Service (AFS–300), 800 Independence Avenue SW., Washington, DC 20591, Telephone: (202) 267–3546; FAX: (202) 267–5230.

SUPPLEMENTARY INFORMATION: The Federal Aviation Administration (FAA) has established an Aviation Rulemaking Advisory Committee (ARAC) (56 FR 2190, January 22, 1991; and 58 FR 9230, February 19, 1993). One area the ARAC deals with is air carrier/general aviation maintenance issues. These issues involve mechanic certification and approved training schools outlined in parts 65 and 147 and the maintenance standards for parts 23, 25, 27, 29, 31, 33, and 35 aircraft, engines, propellers, and their component parts and parallel provisions in parts 21, 43, 91, 121, 125, 127, 129, 133, 135, and 137 of the Federal Aviation Regulations (FAR), which are the responsibility of the FAA Director, Flight Standards Service.

Specifically, the working group's task is the following: Develop a notice of proposed rulemaking which will embody interim policy to standardize the airworthiness determination for civil aircraft parts existing within the civil inventory and which lack acceptable documentation.

Reports

A. Recommend time line(s) for completion of the task, including rationale, for consideration at the meeting of the ARAC to consider air carrier/general aviation maintenance issues held following publication of this notice.

B. Give a detailed conceptual presentation on the task to the ARAC before proceeding with the work stated under item C below.

C. Draft for the ARAC a notice of proposed rulemaking for the task proposing new or revised requirements, a supporting economic analysis and other required analysis, advisory and guidance material, and any other collateral documents the working group determines to be needed.

D. Give a status report on the task at each meeting of the ARAC held to consider air carrier/general aviation maintenance issues.

The Parts Approval Action Team—Phase 3 Working Group will be comprised of experts from those organizations having an interest in the task assigned. A working group member need not necessarily be a representative of one of the member organizations of the ARAC. An individual who has expertise in the subject matter and wishes to become a member of the working group should write the person listed under the caption **FOR FURTHER INFORMATION CONTACT** expressing that desire, describing his or her interest in the task, and the expertise he or she would bring to the working group. The request will be reviewed with the Assistant Chair of the ARAC for air carrier/general aviation maintenance issues and the Chair of the Parts Approval Action Team—Phase 3 Working Group, and the individual will be advised whether or not the request can be accommodated.

The Secretary of Transportation has determined that the formation and use of the ARAC are necessary in the public interest in connection with the performance of duties imposed on the FAA by law. Meetings of the ARAC to consider air carrier/general aviation maintenance issues will be open to the public except as authorized by section 10(d) of the Federal Advisory Committee Act. Meetings of the Parts Approval Action Team—Phase 3 Working Group will not be open to the public, except to the extent that individuals with an interest and expertise are selected to participate. No public announcement of working group meetings will be made.

Issued in Washington, DC, on November 17, 1993.

Benjamin J. Burton, Jr.,

Acting Assistant Executive Director for Air Carrier/General Aviation Maintenance Issues, Aviation Rulemaking Advisory Committee.

[FR Doc. 93–28718 Filed 11–22–93; 8:45 am]

BILLING CODE 4910–13–M

[Summary Notice No. PE–93–50]

Petitions for Exemption; Summary of Petitions Received; Dispositions of Petitions Issued

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of petitions for exemption received and of dispositions of prior petitions.

SUMMARY: Pursuant to FAA's rulemaking provisions governing the application, processing, and disposition of petitions for exemption (14 CFR part 11), this notice contains a summary of certain petitions seeking relief from specified requirements of the Federal Aviation Regulations (14 CFR chapter I), dispositions of certain petitions previously received, and corrections. The purpose of this notice is to improve the public's awareness of, and participation in, this aspect of FAA's regulatory activities. Neither publication of this notice nor the inclusion or omission of information in the summary is intended to affect the legal status of any petition or its final disposition.

DATES: Comments on petitions received must identify the petition docket number involved and must be received on or before December 13, 1993.

ADDRESSES: Send comments on any petition in triplicate to: Federal Aviation Administration, Office of the Chief Counsel, Attn: Rule Docket (AGC–10), Petition Docket No. _____, 800 Independence Avenue SW., Washington, DC 20591.

The petition, any comments received, and a copy of any final disposition are filed in the assigned regulatory docket and are available for examination in the Rules Docket (AGC–10), room 915G, FAA Headquarters Building (FOB 10A), 800 Independence Avenue SW., Washington, DC 20591; telephone (202) 267–3132.

FOR FURTHER INFORMATION CONTACT: Mr. Frederick M. Haynes, Office of Rulemaking (ARM–1), Federal Aviation Administration, 800 Independence Avenue SW., Washington, DC 20591; telephone (202) 267–3939.

This notice is published pursuant to paragraphs (c), (e), and (g) of § 11.27 of part 11 of the Federal Aviation Regulations (14 CFR part 11).

Issued in Washington, DC, on November 17, 1993.

Donald P. Byrne,

Assistant Chief Counsel for Regulations.

Petitions for Exemption

Docket No.: 2610
Petitioner: Chalk's International Airlines
Sections of the FAR Affected: 14 CFR 91.313(a)
Description of Relief Sought/ Disposition: To extend Exemption No. 5428 to continue to permit the petitioner to conduct air carrier flight crew member training in their Grumman HU–16B, which holds a restricted airworthiness certificate.

Docket No.: 27406
Petitioner: Diamond Flight Center
Sections of the FAR Affected: 14 CFR 141.5(b)
Description of Relief Sought: To allow the petitioner to be issued a pilot school certificate with associated ratings for that certificate without meeting the requisite number of applicants for flight certificates required during the 24 months preceding the application.

Docket No.: 27462
Petitioner: Mr. Robert R. Lowry
Sections of the FAR Affected: 14 CFR 121.383(c)
Description of Relief Sought: To allow the petitioner to serve as a pilot in part 121 air carrier operations after his 60th birthday.

Dispositions of Petitions

Docket No.: 26006
Petitioner: Beech Aircraft Corporation
Sections of the FAR Affected: 14 CFR 47.69(b)
Description of Relief Sought/ Disposition: To extend Exemption No. 5125 to continue to permit the petitioner to conduct flights outside the United States. *Grant, October 25, 1993, Exemption No. 5125B*

Docket No.: 27154
Petitioner: Flagler Aviation, Inc.
Sections of the FAR Affected: 14 CFR 105.43 (a) and (d)
Description of Relief Sought/ Disposition: To allow the petitioner's foreign clients to conduct parachute jumping at its facilities without having to comply with the parachute equipment and packing requirements *Partial Grant, November 12, 1993, Exemption No. 5787*

Docket No.: 27340
Petitioner: Mr. William Orr
Sections of the FAR Affected: 14 CFR 65.77
Description of Relief Sought: To allow the petitioner relief from presenting documentary evidence acceptable to the Administrator of his aircraft experience. *Denial, November 12, 1993, Exemption No. 5788*

Docket No.: 27384
Petitioner: The Boeing Company
Sections of the FAR Affected: 14 CFR 25.1435(b)(1)
Description of Relief Sought: To allow the petitioner to conduct hydraulic system tests at 3400 psig in lieu of 3600 psig, since the system relief value cracking pressure setting is 3400 psig. *Grant, October 29, 1993, Exemption No. 5758A*

Docket No.: 27411
Petitioner: Elliott Beecharft of Omaha, Inc.
Sections of the FAR Affected: 14 CFR 91.109 (a) and (b)(3)
Description of Relief Sought/ Disposition: To permit the petitioner's instructors or check airmen to conduct part 135 pilot training and checking in aircraft that are not equipped with a dual set of flight controls. *Denial, November 15, 1993, Exemption No. 5790.*

[FR Doc. 93–28716 Filed 11–22–93; 8:45 am]
BILLING CODE 4910–13–M

RTCA, Inc., Special Committee 178; Requirements for Airport Surface Movement Sensors; Meeting

Pursuant to section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463, 5 U.S.C., appendix I), notice is hereby given for Special Committee 178 meeting to be held January 11–12, 1994 starting at 9 a.m. The meeting will be held at the National Business Aircraft Association, Inc., 1200 18th Street NW., suite 200, Washington, DC 20036.

The agenda for this meeting is as follows: (1) Chairman's introductory remarks; (2) Review and approval of meeting agenda; (3) Approve summary of the eighth meeting held November 8–9, RTCA paper No. XXX–93/SC178–XX (enclosed); (4) Review Draft Report—Review each item. Make additions, deletions, changes as required. The goal is to have a completed final draft at the end of this meeting; (5) Tentative schedule for final draft review and approval process; (6) Recap of session; (7) Other business; (8) Date and place of next meeting.

Attendance is open to the interested public but limited to space available. With the approval of the Chairman, members of the public may present oral statements at the meeting. Persons wishing to present statements or obtain information should contact the RTCA Secretariat, 1140 Connecticut Avenue, NW., suite 1020, Washington, DC 20036; (202) 833–9339. Any member of the public may present a written statement to the committee at any time.

Issued in Washington, DC, on November 16, 1993.

Joyce J. Gillen,

Designated Officer.

[FR Doc. 93–28719 Filed 11–22–93; 8:45 am]
BILLING CODE 4910–13–M

Aviation Rulemaking Advisory Committee Meeting on Air Carrier Operations

AGENCY: Federal Aviation Administration (FAA) DOT.

ACTION: Notice of meeting.

SUMMARY: The FAA is issuing this notice to advise the public of a meeting of the Federal Aviation Administration Aviation Rulemaking Advisory Committee to discuss air carrier operations issues.

DATES: The meeting will be held on December 7, 1993, at 9 a.m.

ADDRESSES: The meeting will be held at the Nassif Building, rooms 8334–8336, Headquarters, Department of Transportation, 400 7th Street SW., Washington, DC 20590.

FOR FURTHER INFORMATION CONTACT: Mrs. Marlene Vermillion, Flight Standards Service, Air Transportation Division (AFS–200), 800 Independence Avenue SW., Washington, DC 20591, telephone (202) 267–8166.

SUPPLEMENTARY INFORMATION: Pursuant to section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463, 5 U.S.C. App II), notice is hereby given of a meeting of the Aviation Rulemaking Advisory Committee to be

held on December 7, 1993, at the Nassif Building, rooms 8334–8336, Department of Transportation, 400 7th Street, SW., Washington, DC 20590. The agenda for this meeting will include progress reports from the Fuel Requirements Working Group, Autopilot Engagement Working Group, and Flight Crewmember Flight/Duty/Rest Requirements Working Group. Each working group Chair will report on the progress of the working group. Attendance is open to the interested public but may be limited to the space available. The public must make arrangements in advance to present oral statements at the meeting or may present written statements to the committee at any time. Arrangements may be made by contacting the person listed under the heading **FOR FURTHER INFORMATION CONTACT.**

Sign and oral interpretation can be made available at the meeting, as well as an assistive listening device, if requested 10 calendar days before the meeting.

Issued in Washington, DC, on November 16, 1993.

David S. Potter,

Assistant Executive Director for Air Carrier Operations, Aviation Rulemaking Advisory Committee.

[FR Doc. 93–28709 Filed 11–22–93; 8:45 am]

BILLING CODE 4910–13–M

RTCA, Inc., Special Committee 180; Design Assurance Guidance for Complex Electronic Hardware Used In Airborne Systems; Meeting

Pursuant to section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463, 5 U.S.C., appendix I), notice is hereby given for Special Committee 180 meeting to be held December 14–16 starting at 8:30 a.m. (first day only) 8 a.m. subsequent days. The meeting will be held at the RTCA conference room, 1140 Connecticut Avenue, NW., suite 1020, Washington, DC 20036.

The agenda for this meeting is as follows: (1) Chairman's introductory remarks; (2) Review and approval of meeting agenda; (3) Approve summary of second meeting held October 25–26; (4) Chairman Presentation on Outcome of Technical Management Committee Meeting Concerning Draft Revision of Terms Reference; (5) Review data from EUROCAE; (6) Review working group assignments; (7) Develop working group flow chart; (8) Preliminary W8S; (9) Review SC–180 Assets; (10) Review of action items from last meeting; (11) Other business; (12) Date and place of next meeting.

Attendance is open to the interested public but limited to space available. With the approval of the Chairman, members of the public may present oral statements at the meeting. Persons wishing to present statements or obtain information should contact the RTCA Secretariat, 1140 Connecticut Avenue NW., suite 1020, Washington, DC 20036; (202) 833–9339. Any member of the public may present a written statement to the committee at any time.

Issued in Washington, DC, on November 16, 1993.

Joyce J. Gillen,

Designated Officer.

[FR Doc. 93–28703 Filed 11–22–93; 8:45 am]

BILLING CODE 4910–13–M

RTCA, Inc.; Federal Advisory Committee Meeting

Pursuant to section 10(a)(2) of the Federal Advisory Committee Act (Public Law 92-463, 5 U.S.C., appendix I), notice is hereby given for the following meeting:

The RTCA Board of Directors will meet as a Federal Advisory Committee on December 7, 1993 at 10 a.m in the RTCA conference room, 1140 Connecticut Avenue, NW., suite 1020, Washington, DC to approve the RTCA Task Force 2 report.

Attendance is open to the interested public but limited to space available. With the approval of the Chairman, members of the public may present oral statements at the meeting. Persons wishing to present statements or obtain information should contact the RTCA Secretariat, 1140 Connecticut Avenue NW., suite 1020, Washington, DC 20036; (202) 833–9339. Any member of the public may present a written statement to the committee at any time.

Issued in Washington, DC, on November 16, 1993.

Joyce J. Gillen,

Designated Officer.

[FR Doc. 93–28720 Filed 11–22–93; 8:45 am]

BILLING CODE 4910–13–M

Intent To Rule on Application To Impose and Use the Revenue From a Passenger Facility Charge (PFC) at Dubuque Regional Airport, Dubuque, IA

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of intent to rule on application.

SUMMARY: The FAA proposes to rule and invites public comment on the application to impose and use the revenue from a PFC at Dubuque Regional Airport under the provisions of the Aviation Safety and Capacity expansion Act of 1990 (title IX of the Omnibus Budget Reconciliation Act of 1990) (Public Law 101–508) and part 158 of the Federal Aviation Regulations (14 CFR part 158).

DATES: Comments must be received on or before December 23, 1993.

ADDRESSES: Comments on this application may be mailed or delivered in triplicate to the FAA at the following address: Federal Aviation Administration, Central Region, Airports Division, 601 E. 12th Street. Kansas City, Missouri 64106.

In addition, one copy of any comments submitted to the FAA must be mailed or delivered to Mr. Robert W. O'Brien, Jr., Airport Manager, Dubuque Regional Airport, at the following address: Dubuque Regional Airport, 11000 Airport Road, Dubuque, Iowa 52003–9555.

Air carriers and foreign air carriers may submit copies of written comments previously provided to the City of Dubuque, Dubuque Regional airport, under § 158.23 of part 158.

FOR FURTHER INFORMATION CONTACT: Ellie Anderson, PFC Coordinator, FAA, Central Regional, 601 E. 12th Street, Kansas City, Missouri 64106, (816) 426–4728. The application may be reviewed in person at this same location.

SUPPLEMENTARY INFORMATION: The FAA proposes to rule and invites public comment on the application to impose and use the revenue from a PFC at the Dubuque Regional Airport under the provisions of the Aviation Safety and Capacity Expansion Act of 1990 (title IX of the Omnibus Budget Reconciliation Act of 1990) (Public Law 101–508) and part 158 of the Federal Aviation Regulations (14 CFR part 158).

On November 9, 1993, the FAA determined that the application to impose and use the revenue from a PFC submitted by the City of Dubuque, Iowa, was substantially complete within the requirement of § 158.25 of part 158. The FAA will approve or disapprove the application, in whole or in part, no later than February 8, 1994.

The following is a brief overview of the application.

Level of the proposed PFC: $3.00

Proposed charge effective date: February 1, 1994

Proposed charge expiration date: November 1, 1996

Total estimated PFC revenue: $225,326

Brief description of proposed project(s):

Acquisition of snow removal equipment; airport layout plan; ARFF radio system; air service study;

airfield beacon; signage; airline terminal HVAC; ATVN training; non revenue parking lot rehabilitation.

Class or classes of air carriers which the public agency has requested not be required to collect PFCs: None.

Any person may inspect the application in person at the FAA office listed above under **FOR FURTHER INFORMATION CONTACT.**

In addition, any person may, upon request, inspect the application, notice and other documents germane to the application in person at the Dubuque Regional Airport.

Issued in Kansas City, Missouri, on November 10, 1993.

Wayne E. Halter,

Acting Manager, Airports Division, Central Region.

[FR Doc. 93–28712 Filed 11–22–93; 8:45 am]

BILLING CODE 4910–13–M

Intent To Rule on Application To Impose a Passenger Facility Charge (PFC) at Lewiston-Nez Perce County Airport, Lewiston, ID

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of intent to rule on application.

SUMMARY: The FAA proposes to rule and invites public comment on the application to impose a PFC at Lewiston-Nez Perce County Airport under the provisions of the Aviation Safety and Capacity Expansion Act of 1990 (title IX of the Omnibus Budget Reconciliation Act of 1990) (Public Law 101–508) and part 158 of the Federal Aviation Regulations (14 CFR part 158).

DATES: Comments must be received on or before December 23, 1993.

ADDRESSES: Comments on this application may be mailed or delivered in triplicate to the FAA at the following address: J. Wade Bryant, Manager, Seattle Airports District Office, SEA–ADO, Federal Aviation Administration, 1601 Lind Avenue SW., suite 250, Renton, WA 98055–4056.

In addition, one copy of any comments submitted to the FAA must be mailed or delivered to Mr. Robin L. Turner, Airport Manager of the Lewiston-Nez Perce County Airport at the following address: Airport Administration Building, 412 Burrell, Lewiston, ID 83501

Air carriers and foreign air carriers may submit copies of written comments previously provided to Mr. Robin Turner under § 158.23 of part 158.

FOR FURTHER INFORMATION CONTACT: Ms. Sandra Simmons, Civil Engineer, (206) 227–2656; Seattle Airports District Office, SEA–ADO; Federal Aviation Administration, 1601 Lind Avenue SW., suite 250; Renton, WA 98055–4056. The application may be reviewed in person at this same location.

SUPPLEMENTARY INFORMATION: The FAA proposes to rule and invites public comment on the application to impose a PFC at Lewiston-Nez Perce County Airport under the provisions of the Aviation Safety and Capacity Expansion Act of 1990 (title IX of the Omnibus Budget Reconciliation Act of 1990) (Public Law 101–508) and part 158 of the Federal Aviation Regulations (14 CFR part 158).

On October 27, 1993, the FAA determined that the application to impose a PFC submitted by the City of Lewiston and Nez Perce County, Idaho was substantially complete within the requirements of § 158.25 of part 158. The FAA will approve or disapprove the application, in whole or in part, no later than February 4, 1994.

The following is a brief overview of the application.

Level of the proposed PFC: $3.00

Proposed charge effective date: April 1, 1994

Proposed charge expiration date: January 31, 1997

Total estimated PFC revenue: $229,610.00

Brief description of proposed project(s): Expansion/renovation/remodeling of the terminal building and taxiway pavement rehabilitation.

Class or classes of air carriers which the public agency has requested not be required to collect PFCs: Air Taxi/Commercial Operators when enplaning revenue passengers in limited, irregular, special service air taxi/commercial operations such as air ambulance services, non-stop sightseeing flights that begin and end at the airport and are concluded within a 25 mile radius of the airport, and other limited irregular, special service operations.

Any person may inspect the application in person at the FAA office listed above under **"FOR FURTHER INFORMATION CONTACT"** and at the FAA regional Airports office located at: Federal Aviation Administration, Northwest Mountain Region, Airports Division, ANM–600, 1601 Lind Avenue SW., suite 540 Renton, WA 98055–4056.

In addition, any person may, upon request, inspect the application, notice and other documents germane to the application in person at the Lewiston-Nez Perce County Airport.

Edward G. Tatum,

Manager, Airports Division, Northwest Mountain Region.

[FR Doc. 93–28714 Filed 11–22–93; 8:45 am]

BILLING CODE 4910–13–M

RTCA, Inc., Special Committee 181; Standards of Navigation Performance; Meeting

Pursuant to section 10(a)(2) of the Federal Advisory Committee Act (Public Law 92–463, 5 U.S.C., appendix I), notice is hereby given for Special Committee 181 meeting to be held December 7–8 starting at 9:30 a.m. The meeting will be held at the RTCA conference room, 1140 Connecticut Avenue NW., suite 1020, Washington, DC 20036.

The agenda for this meeting is as follows: (1) Introductory remarks; (2) Review of terms of reference; (3) Identify goals, develop work program and examine milestones; (4) Assign tasks; (5) Other business; (6) Date and place of next meeting.

Attendance is open to the interested public but limited to space available. With the approval of the Chairman, members of the public may present oral statements at the meeting. Persons wishing to present statements or obtain information should contact the RTCA Secretariat, 1140 Connecticut Avenue NW., suite 1020, Washington, DC 20036; (202) 833–9339. Any member of the public may present a written statement to the committee at any time.

Issued in Washington, DC, on November 16, 1993.

Joyce J. Gillen,

Designated Officer.

[FR Doc. 93–28708 Filed 11–22–93; 8:45 am]

BILLING CODE 4910–13–M

Personnel Parachutes Assemblies

AGENCY: Federal Aviation Administration, DOT.

ACTION: Notice of availability.

SUMMARY: This notice announces the availability of and requests comments on a proposed technical standard order (TSO) pertaining to personnel parachute assemblies. The proposed TSO prescribes the minimum performance standards that personnel parachute assemblies must meet in order to be identified with the marking "TSO–C23d."

DATES: Comments must be received on or before February 14, 1994.

ADDRESSES: Send all comments on the proposed technical standard order to: Technical Analysis Branch, AIR–120, Aircraft Engineering Division, Aircraft Certification Service—File No. TSO–C23d, Federal Aviation Administration, 800 Independence Avenue, SW., Washington, DC 20591. Or deliver comments to: Federal Aviation Administration, room 806, 800 Independence Avenue SW., Washington, DC 20591.

FOR FURTHER INFORMATION CONTACT:

Ms. Bobbie J. Smith, Technical Analysis Branch, AIR–120, Aircraft Engineering Division, Aircraft Certification Service, Federal Aviation Administration, 800 Independence Avenue SW., Washington, DC 20591, Telephone (202) 267–9546.

SUPPLEMENTARY INFORMATION:

Comments Invited

Interested persons are invited to comment on the proposed TSO listed in this notice by submitting such written data, views, or arguments as they desire to the above specified address. Comments received on the proposed technical standard order may be examined, before and after the comment closing date, in room 806, FAA Headquarters Building (FOB–10A), 800 Independence Avenue, SW., Washington, DC 20591, weekdays except Federal holidays, between 8:30 a.m. and 4:30 p.m. All communications received on or before the closing date for comments specified above will be considered by the Director of the Aircraft Certification Service before issuing the final TSO.

Background

The proposed TSO–C23d incorporates SAE AS 8015B, "Minimum Performance Standards for Parachute Assemblies and Components, Personnel". The proposed TSO will allow the use of dual harness parachutes.

How To Obtain Copies

A copy of the proposed TSO–C23d may be obtained by contacting the person listed in **FOR FURTHER INFORMATION CONTACT.** Proposed TSO–C23d incorporates the Society of Automotive Engineers, Inc. (SAE) Aerospace Standard (AS) Document No. AS 8015B, dated July 7, 1992. Copies of SAE AS 8015B may be purchased from the Society of Automotive Engineers, Inc., Department 331, 400 Commonwealth Drive, Warrendale, PA 15096.

Issued in Washington, DC, on November 12, 1993.

John K. McGrath,

Manager, Aircraft Engineering Division, Aircraft Certification Service.

[FR Doc. 93–28715 Filed 11–22–93; 8:45 am]

BILLING CODE 4910–13–M

National Highway Traffic Safety Administration

Announcing the Fourth Meeting of the Motor Vehicle Titling, Registration and Salvage Advisory Committee

AGENCY: National Highway Traffic Safety Administration (NHTSA), Department of Transportation (DOT).

ACTION: Meeting announcement.

SUMMARY: This notice announces the fourth meeting of the Motor Vehicle Titling, Registration, and Salvage Advisory Committee. The Committee was established as required by section 140 of the Anti Car Theft Act of 1992, Public Law 102–519, and in accordance with the Federal Advisory Committee Act, for the purpose of studying problems related to motor vehicle titling, registration, and controls over motor vehicle salvage which may affect the motor vehicle theft problem. The Committee will develop and submit a report to the President, the Congress, and the chief executive of each State concerning the result of this study, which will include recommendations to solve these problems. At this meeting the Committee will discuss flood damaged vehicles, exportation of motor vehicles, false reports of stolen vehicles, and the need for enforcement mechanisms. The Committee will also finalize all other Committee business.

DATE AND TIME: The meeting is scheduled to begin at 10 a.m. on Monday, December 6, 1993, and conclude at 4 p.m. on Wednesday, December 8, 1993.

ADDRESSES: The meeting will be held in room 2230, of the Department of Transportation Building, which is located at 400 Seventh street SW., Washington, DC.

SUPPLEMENTARY INFORMATION: In April 2993, the Motor Vehicle Titling, Registration, and Salvage Advisory Committee was established as required by section 140 of the Anti Car Theft Act of 1992, Public Law 102–519. The purpose of the Committee is to study problems which relate to motor vehicle titling, registration, and vehicle salvage controls, including the lack of uniformity in State laws, which may contribute to motor vehicle theft and fraud problems.

The Committee will prepare a report containing the results of the study, including appropriate recommendations to solve the problems identified. The report shall be submitted to the President, the Congress, and to the chief executive officer of each State not later than April 1994.

This meeting is open to the public; however, participation will be determined by the Committee Chairperson.

A public reference file (P.F. 93–001) has been established to contain products of the Committee and will be open to the public during the hours of 9:30 a.m. to 4 p.m. at the National Highway Traffic Safety Administration's Technical Reference Division in room 5108 at 400 Seventh Street SW., Washington, DC 20590, telephone (202) 366–2768.

FOR FURTHER INFORMATION CONTACT: Richard C. Morse, Odometer Fraud Staff, Office of the Associate Administrator for Enforcement, National Highway Traffic Safety Administration, NEF–20, room 5321, 400 Seventh Street SW., Washington, DC 20590, Phone: 202–366–4761.

Issued on: November 16, 1993.

William A. Boehly,

Associate Administrator for Enforcement.

[FR Doc. 93–28651 Filed 11–22–93; 8:45 am]

BILLING CODE 4910–59–M

DEPARTMENT OF THE TREASURY

Public Information Collection Requirements Submitted to OMB for Review

November 16, 1993.

The Department of Treasury has submitted the following public information collection requirement(s) to OMB for review and clearance under the Paperwork Reduction Act of 1980, Public Law 96–511. Copies of the submission(s) may be obtained by calling the Treasury Bureau Clearance Officer listed. Comments regarding this information collection should be addressed to the OMB reviewer listed and to the Treasury Department Clearance Officer, Department of the Treasury, room 3171 Treasury Annex, 1500 Pennsylvania Avenue, NW., Washington, DC 20220.

Internal Revenue Service

OMB Number: 1545–1002.
Form Number: IRS Form 8621.
Type of Review: Extension.
Title: Return by a Shareholder of a Passive Foreign Investment Company or Qualified Electing Fund.

Description: Form 8621 is filed by a U.S. person who owns stock in a foreign investment company. The form is used to report income, make an election to extend the time for payment of tax, and to pay an additional tax and interest amount. The IRS uses Form 8621 to determine if these shareholders have correctly reported amounts of income, made the election correctly, and have correctly computed the additional tax and interest amount.

Respondents: Individuals or households, Businesses or other for-profit.

Estimated Number of Respondents/ Recordkeeping: 2,000.

Estimated Burden Hours Per Respondent/Recordkeeper:

Recordkeeping—12 hrs., 12 min.

Learning about the law of the form—1 hr., 41 min.

Preparing and sending the form to the IRS—1 hr., 58 min.

Frequency of Response: Annually.

Estimated Total Reporting/ Recordkeeping Burden: 31,680 hours.

Clearance Officer: Garrick Shear (202) 622–3869, Internal Revenue Service, Room 5571, 1111 Constitution Avenue, NW., Washington, DC 20224.

OMB Reviewer: Milo Sunderhauf (202) 395–6880, Office of Management and Budget, Room 3001, New Executive Office Building, Washington, DC 20503.

Lois K. Holland,

Departmental Reports Management Officer.

[FR Doc. 93–28670 Filed 11–22–93; 8:45 am]

BILLING CODE 4830–01–P

Public Information Collection Requirements Submitted to OMB for Review

November 16, 1993.

The Department of Treasury has submitted the following public information collection requirement(s) to OMB for review and clearance under the Paperwork Reduction Act of 1980, Public Law 96–511. Copies of the submission(s) may be obtained by calling the Treasury Bureau Clearance Officer listed. Comments regarding this information collection should be addressed to the OMB reviewer listed and to the Treasury Department Clearance Officer, Department of the Treasury, room 3171 Treasury Annex, 1500 Pennsylvania Avenue, NW., Washington, DC 20220.

U.S. Customs Service

OMB Number: 1515–0135.

Form Number: None.

Type of Review: Extension.

Title: Required Records for Smelting and Refining Warehouse.

Description: Each manufacturer engaged in smelting or refining must file an annual statement with the Regional Director, Regulatory Audit, showing any material change in the character of the metal-bearing materials smelted or refined, or changes in the method of smelting or refining. Also, the records must show the receipt and disposition of each shipment.

Respondents: Businesses or other for-profit.

Estimated Number of Respondents/ Recordkeepers: 15.

Estimated Burden Hours Per Respondent: 87 hours, 8 minutes.

Frequency of Response: Annually.

Estimated Total Reporting Burden: 1,325 hours.

Clearance Officer: Ralph Meyer (202) 927–1552, U.S. Customs Service, Paperwork Management Branch, room 6316, 1301 Constitution Avenue, NW., Washington, DC 20229.

OMB Reviewer: Milo Sunderhauf (202) 395–6880, Office of Management and Budget, room 3001, New Executive Office Building, Washington, DC 20503.

Lois K. Holland,

Departmental Reports Management Officer.

[FR Doc. 93–28671 Filed 11–22–93; 8:45 am]

BILLING CODE 4820–02–M

Treasury Advisory Committee on Commercial Operations of the U.S. Customs Service

AGENCY: Department Offices, Treasury.

ACTION: Notice of meeting.

SUMMARY: This notice announces the date of the next meeting and the agenda for consideration by the Treasury Advisory Committee on Commercial Operations of the U.S. Customs Service.

DATES: The next meeting of the Treasury Advisory Committee on Commercial Operations of the U.S. Customs Service will be held on Thursday, December 9, 1993, at 9:30 a.m. in the U.S. Treasury Department, Washington, DC. The precise location of the meeting is yet to be determined and may be ascertained by the meeting date by contacting the persons named at the end of this notice.

FOR FURTHER INFORMATION CONTACT:. Dennis M. O'Connell, Director, Office of Tariff and Trade Affairs, Office of the Assistant Secretary (Enforcement), room 4004, Department of the Treasury, 1500 Pennsylvania Avenue, NW., Washington, DC 20220. Tel.: (202) 622–0220.

SUPPLEMENTARY INFORMATION: The preliminary agenda to be considered at the meeting is as follows:

1. The Customs Modernization Act and Informed Compliance Legislation.
2. Status of the North American Free Trade Agreement.
3. Formation of the Customs reorganization team and development of a work plan for restructuring.
4. Briefing by the Chief Textile Negotiator on Administration initiatives to stop textile transshipment.
5. Other new business.

The agenda may be supplemented or otherwise amended prior to the meeting date.

The meeting is open to the public; however, it is necessary for any person other than an Advisory Committee member who wishes to attend the meeting to give advance notice. In order to be admitted to the meeting, contact Ms. Laura Wilkins at (202) 622–1431 or Ms. Theresa Manning at (202) 622–0220 no later than Thursday, December 2, 1993.

Dated: November 16, 1993.

John P. Simpson,

Deputy Assistant Secretary (Regulatory, Tariff and Trade Enforcement).

[FR Doc. 93–28665 Filed 11–22–93; 8:45 am]

BILLING CODE 4810–25–M

DEPARTMENT OF VETERANS AFFAIRS

Information Collection Under OMB Review: Application for Educational Assistance Test Program Benefits (Section 901, PL 96–342), VA Form 22–8889

AGENCY: Department of Veterans Affairs.

ACTION: Notice.

The Department of Veterans Affairs has submitted to OMB the following proposal for the collection of information under the provisions of the Paperwork Reduction Act (44 U.S.C. chapter 35). This document lists the following information: (1) The title of the information collection, and the Department form number(s), if applicable; (2) a description of the need and its use; (3) who will be required or asked to respond; (4) an estimate of the total annual reporting hours, and recordkeeping burden, if applicable; (5) the estimated average burden hours per respondent; (6) the frequency of response; and (7) an estimated number of respondents.

ADDRESSES: Copies of the proposed information collection and supporting documents may be obtained from Janet G. Byers, Veterans Benefits Administration (20A5), Department of Veterans Affairs, 810 Vermont Avenue,

NW., Washington, DC 20420 (202) 233–3021.

Comments and questions about the items on the list should be directed to VA's OMB Desk Officer, Joseph Lackey, NEOB, room 3002, Washington, DC 20503, (202) 395–7316. Do not send requests for benefits to this address.

DATES: Comments on the information collection should be directed to the OMB Desk Officer within 30 days of this notice.

Dated: November 9, 1993.

By direction of the Secretary.

B. Michael Berger,

Director, Records Management Service.

Extension

1. Application for Educational Assistance Test Program Benefits (Section 901, Pub. L. 96–342), VA Form 22–8889.

2. The form is used by individuals under the Educational Assistance Test Program to apply for educational benefits. The information is used by VA to determine eligibility for benefits.

3. Individuals or households.

4. 175 hours.

5. 30 minutes.

6. On occasion.

7. 350 respondents.

[FR Doc. 93–28696 Filed 11–22–93; 8:45 am]

BILLING CODE 8320–01–M

Information Collection Under OMB Review: Report of Accidental Injury in Support of Claim for Compensation or Pension, VA Form 21–4176

AGENCY: Department of Veterans Affairs.

ACTION: Notice.

The Department of Veterans Affairs has submitted to OMB the following proposal for the collection of information under the provisions of the Paperwork Reduction Act (44 U.S.C. chapter 35). This document lists the following information:

(1) The title of the information collection, and the Department form number(s) if applicable;

(2) A description of the need and its use;

(3) Who will be required or asked to respond;

(4) An estimate of the total annual reporting hours, and recordkeeping burden, if applicable;

(5) The estimated average burden hours per respondent;

(6) The frequency of response; and

(7) An estimated number of respondents.

ADDRESSES: Copies of the proposed information collection and supporting documents may be obtained from Janet G. Byers, Veterans Benefits Administration (20A5), Department of Veterans Affairs, 810 Vermont Avenue, NW., Washington, DC 20420 (202) 233–3021.

Comments and questions about the items on the list should be directed to VA's OMB Desk Officer, Joseph Lackey, NEOB, room 3002, Washington, DC 20503, (202) 395–7316. Do not send requests for benefits to this address.

DATES: Comments on the information collection should be directed to the OMB Desk Officer within 30 days of this notice.

Dated: November 9, 1993.

By direction of the Secretary.

B. Michael Berger,

Director, Records Management Service.

Revision

1. Report of Accidental Injury in Support of Claim for Compensation or Pension, VA Form 21–4176.

2. The form is used to obtain information regarding accidents resulting in the disability upon which a claim is based and to give the veteran an opportunity to provide information based on his/her own knowledge regarding the accident. The information is used by VA in determining eligibility for benefits.

3. Individuals or households.

4. 2,200 hours.

5. 30 minutes.

6. On occasion.

7. 4,400 respondents.

[FR Doc. 93–28698 Filed 11–22–93; 8:45 am]

BILLING CODE 8320–01–M

Information Collection Under OMB Review: Report of Automatic Manufactured Home and/or Lot Loan, VA Form 26–8149

AGENCY: Department of Veterans Affairs.

ACTION: Notice.

The Department of Veterans Affairs has submitted to OMB the following proposal for the collection of information under the provisions of the Paperwork Reduction Act (44 U.S.C. chapter 35). This document lists the following information: (1) The title of the information collection, and the Department form number(s), if applicable; (2) a description of the need and its use; (3) who will be required or asked to respond; (4) an estimate of the total annual reporting hours, and recordkeeping burden, if applicable; (5) the estimated average burden hours per respondent; (6) the frequency of response; and (7) an estimated number of respondents.

ADDRESSES: Copies of the proposed information collection and supporting documents may be obtained from Janet G. Byers, Veterans Benefits Administration (20A5), Department of Veterans Affairs, 810 Vermont Avenue, NW., Washington, DC 20420, (202) 233–3021.

Comments and questions about the items on the list should be directed to VA's OMB Desk Officer, Joseph Lackey, NEOB, room 3002, Washington, DC 20503, (202) 395–7316. Do not send requests for benefits to this address.

DATES: Comments on the information collection should be directed to the OMB Desk Officer by December 23, 1993.

Dated: November 9, 1993.

By direction of the Secretary.

B. Michael Berger,

Director, Records Management Service.

Extension

1. Report of Automatic Manufactured Home and/or Lot Loan, VA Form 26–8149.

2. The form is used by lenders authorized to make manufactured home and/or lot loans on the automatic basis. The information is used by VA to determine that all requirements are met before issuing evidence of guaranty.

3. Businesses or other for-profit—Small business or organizations.

4. 39 hours.

5. 30 minutes.

6. On occasion.

7. 78 respondents.

[FR Doc. 93–28702 Filed 11–22–93; 8:45 am]

BILLING CODE 8320–01–M

Information Collection Under OMB Review: Request for Verification of Employment, VA Form 26–8497

AGENCY: Department of Veterans Affairs.

ACTION: Notice.

The Department of Veterans Affairs has submitted to OMB the following proposal for the collection of information under the provisions of the Paperwork Reduction Act (44 U.S.C. chapter 35). This document lists the following information: (1) The title of the information collection, and the Department form number(s), if applicable; (2) a description of the need and its use; (3) who will be required or asked to respond; (4) an estimate of the total annual reporting hours, and recordkeeping burden, if applicable; (5) the estimated average burden hours per respondent; (6) the frequency of response; and (7) an estimated number of respondents.

ADDRESSES: Copies of the proposed information collection and supporting documents may be obtained from Janet G. Byers, Veterans Benefits Administration (20A5), Department of Veterans Affairs, 810 Vermont Avenue, NW., Washington, DC 20420 (202) 233–3021.

Comments and questions about the items on the list should be directed to VA's OMB Desk Officer, Joseph Lackey, NEOB, room 3002, Washington, DC 20503, (202) 395–7316. Do not send requests for benefits to this address.

DATES: Comments on the information collection should be directed to the OMB Desk Officer by December 23, 1993.

Dated: November 9, 1993.

By direction of the Secretary.

B. Michael Berger,

Director, Records Management Service.

Extension

1. Request for Verification of Employment, VA Form 26–8497
2. The form is used by lenders to verify a loan applicant's income and employment information when making guaranteed and insured loans. The use of this form is optional since any comprehensible form of independent verification is acceptable, provided all information contained on VA Form 26–94497 is furnished.
3. Business or other for-profit
4. 52,667 hours.
5. 10 minutes.
6. On occasion.
7. 316,000 respondents.

[FR Doc. 93–28699 Filed 11–22–93; 8:45 am]

BILLING CODE 8320–01–M

Information Collection Under OMB Review: Application for Release From Personal Liability to the Government on a Home Loan, VA Form 26–6381

AGENCY: Department of Veterans Affairs.

ACTION: Notice.

The Department of Veterans Affairs has submitted to OMB the following proposal for the collection of information under the provisions of the Paperwork Reduction Act (44 U.S.C. chapter 35). This document lists the following information: (1) The title of the information collection, and the Department form number(s), if applicable; (2) a description of the need and its use; (3) who will be required or asked to respond; (4) an estimate of the total annual reporting hours, and recordkeeping burden, if applicable; (5) the estimated average burden hours per respondent; (6) the frequency of response; and (7) an estimated number of respondents.

ADDRESSES: Copies of the proposed information collection and supporting documents may be obtained from Janet G. Byers, Veterans Benefits Administration (20A5), Department of Veterans Affairs, 810 Vermont Avenue, NW., Washington, DC 20420 (202) 233–3021.

Comments and questions about the items on the list should be directed to VA's OMB Desk Officer, Joseph Lackey, NEOB, room 3002, Washington, DC 20503, (202) 395–7316. Do not send requests or benefits to this address.

DATES: Comments on the information collection should be directed to the OMB Desk Officer by December 23, 1993.

Dated: November 9, 1993.

By direction of the Secretary.

B. Michael Berger,

Director, Records Management Service.

Extension

1. Application for Release from Personal Liability to the Government on a Home Loan, VA Form 26–6381
2. The form is completed by veterans who are selling their VA-guaranteed homes by assumption rather than requiring the purchaser to obtain their own financing to pay off the loan. The information is used by VA to determine assumption approval.
3. Individuals or households—Businesses or other for-profit.
4. 1,328 hours.
5. 10 minutes.
6. On occasion.
7. 7,973 respondents.

[FR Doc. 93–28700 Filed 11–22–93; 8:45 am]

BILLING CODE 8320–01–M

Information Collection Under OMB Review: Request to Lender for Status of Loan Account-LCS, VA Form 26–8778

AGENCY: Department of Veterans Affairs.

ACTION: Notice.

The Department of Veterans Affairs has submitted to OMB the following proposal for the collection of information under the provisions of the Paperwork Reduction Act (44 U.S.C. chapter 35). This document lists the following information:

(1) The title of the information collection, and the Department form number(s), if applicable;

(2) A description of the need and its use;

(3) Who will be required or asked to respond;

(4) An estimate of the total annual reporting hours, and recordkeeping burden, if applicable;

(5) The estimated average burden hours per respondent;

(6) The frequency of response; and

(7) An estimated number of respondents.

ADDRESSES: Copies of the proposed information collection and supporting documents may be obtained from Janet G. Byers, Veterans Benefits Administration (20A5), Department of Veterans Affairs, 810 Vermont Avenue, NW., Washington, DC 20420 (202) 233–3021.

Comments and questions about the items on the list should be directed to VA's OMB Desk Officer, Joseph Lackey, NEOB, room 3002, Washington, DC 20503, (202) 395–7316. Do not send requests for benefits to this address.

DATES: Comments on the information collection should be directed to the OMB Desk Officer within 30 days of this notice.

Dated: November 9, 1993.

By direction of the Secretary.

B. Michael Berger,

Director, Records Management Service.

Extension

1. Request to Lender for Status of Loan Account-LCS, VA Form 26–8778
2. The form is used by VA to obtain pertinent data from the servicer of guaranteed or insured loans and vendee loans sold with VA repurchase agreement on the status of loans in default. The information is used to assure that necessary action is taken to cure the default.
3. Small businesses or organizations.
4. 29,167 hours.
5. 10 minutes.
6. On ocassion.
7. 175,000 respondents.

[FR Doc. 93–28697 Filed 11–22–93; 8:45 am]

BILLING CODE 8320–01–M

federal register

Tuesday
November 23, 1993

Part II

Department of Health and Human Services

Food and Drug Administration

21 CFR Part 820
Medical Devices; Current Good Manufacturing Practice (CGMP) Regulations; Proposed Revisions; Request for Comments; Proposed Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR PART 820

[Docket No. 90N–0172]

Medical Devices; Current Good Manufacturing Practice (CGMP) Regulations; Proposed Revisions; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing to revise the current good manufacturing practice (CGMP) regulations for medical devices to: Replace quality assurance program requirements with quality system requirements that include design, purchasing, and servicing controls; clarify recordkeeping requirements for device failure and complaint investigations; clarify requirements for qualifying, verifying, and validating processes and specification changes; and clarify requirements for evaluating quality data and correcting quality problems. In addition, FDA has also, through reorganization and modification of terms, revised the CGMP requirements for medical devices to ensure that they are compatible with specifications for quality systems contained in international quality standards, ISO 9001 "Quality Systems Part 1. Specification for Design/Development, Production, Installation, and Servicing" (Ref. 1), and other applicable international standards, thereby integrating international quality system terminology into proposed CGMP requirements.

DATES: Submit written comments by February 22, 1994. FDA is proposing that any final rule that may issue based upon this proposal become effective 180 days following its publication.

ADDRESSES: Submit written information and comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, rm. 1–23, 12420 Parklawn Dr., Rockville, MD 20857. Submit written requests for single copies of this document to the Division of Small Manufacturers Assistance (HFZ–220), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Please provide two self-addressed envelopes to assist the division in processing your requests. All comments and requests should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: William F. Hooten, Center for Devices and Radiological Health (HFZ–300), Food and Drug Administration, 2098 Gaither Rd., Rockville, MD 20850, 301–594–4646.

SUPPLEMENTARY INFORMATION

I. Background

Manufacturers establish and follow quality systems to help ensure that their products consistently meet applicable requirements and specifications. The quality systems for FDA-regulated products (e.g., food, drugs, and devices) are known as CGMP's. CGMP requirements for devices (21 CFR part 820) were first authorized by section 520(f) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360j(f)), which was among the authorities of the Medical Device Amendments of 1976 (Pub. L. 94–295) to the act.

Pursuant to section 520(f) of the act, FDA issued final regulations in the **Federal Register** of July 21, 1978 (43 FR 31508), prescribing CGMP requirements for the methods used in, and the facilities and controls used for, the manufacture, packing, storage, and installation of medical devices. These regulations became effective December 18, 1978, and are codified at part 820. Except for editorial changes to update organizational references in the regulations and revisions to the list of critical devices that was included in the preamble to the final regulations, the device CGMP requirements have not been revised since 1978. This proposed rule is the result of an effort begun in 1990 to revise these regulations.

On November 28, 1990, the Safe Medical Devices Act of 1990 (the SMDA) (Pub. L. 101–629) became law. The SMDA amended section 520(f)(1)(A) of the act to provide clear authority to add preproduction design validation controls to the device CGMP regulations and also added a new section 803 to the act (21 U.S.C. 383) which encourages FDA to work with foreign countries toward mutual recognition of CGMP requirements.

This action is being taken pursuant to those provisions of the SMDA, and in response to notices that appeared in the **Federal Register** of April 25, 1990 (55 FR 17502), and in the **Federal Register** of April 17, 1991 (56 FR 15626), that announced meetings of the agency's Device Good Manufacturing Practice Advisory Committee, at which the need for revisions to the CGMP regulations was explored, and an advance notice of proposed rulemaking (ANPRM) that appeared in the **Federal Register** of June 15, 1990 (55 FR 24544), that announced the agency's intent to revise the CGMP regulations. The agency also announced the availability of a document that appeared in the **Federal Register** of November 30, 1990 (55 FR 49644), entitled "Medical Devices; Current Good Manufacturing Practices (CGMP) Regulations Document; Suggested Changes; Availability," (Ref. 2) (hereinafter referred to as the November 1990 information document) and solicited comments from the public about the document. The agency has met to discuss current good manufacturing practice development with representatives of the European Community (EC), with members of the European Committee for Standardization who have developed the EC's current quality system standards for medical devices, and with representatives of the Canadian Ministry of Health and Welfare and the Japanese Ministry of Health and Welfare. The agency has also participated in numerous industry and professional association seminars and workshops where the proposed revisions of FDA's CGMP regulations were the focus of the meetings.

Thus, FDA's decision to revise the CGMP regulations is based on changes in the law by the SMDA, the agency's discussions with others including its Device Good Manufacturing Practice Advisory Committee, responses to the **Federal Register** notices on this matter, FDA's analysis of recall data, its experience with the regulatory application of the current device CGMP regulations, and its assessment of international quality standards.

II. Summary and Rationale of Proposed Changes

FDA is proposing to add design, purchasing, and servicing controls; modify the critical device requirements; revise certain existing requirements to clarify the intent of the requirements; and harmonize the CGMP regulations for medical devices with quality system specifications in the ISO 9001 International Quality Standard, "Quality Systems Part 1. Specification for Design/Development, Production, Installation, and Servicing" (Ref. 1).

A. Design Controls

Over the last 9 years, FDA has identified lack of design controls as one of the major causes of device recalls (Ref. 3). The intrinsic quality of devices, including their safety and effectiveness, is established during the design phase. Thus, FDA believes that unless

appropriate design controls are observed during preproduction stages of development, a finished device may be neither safe nor effective for its intended use. The SMDA provides FDA with the authority to add preproduction design validation controls to the device CGMP regulations. Based on its experience with administering the CGMP regulations, which currently do not include preproduction design validation controls, the agency is concerned that the current regulations provide less than an appropriate level of assurance that devices will be safe and effective. Therefore, FDA is proposing to add general requirements for design controls to the device CGMP regulations for all class III and II devices and several class I devices.

i. Congressional Hearings

As early as 1984, Congress began holding hearings on medical device failures and FDA's apparent inability to anticipate or address problems within the industry under the 1976 amendments. These hearings focused on deaths resulting from the use of cardiac pacemaker leads which had malfunctioned due to design problems. (See the March 13, 1984, hearing of the House of Representatives' Committee on Energy and Commerce's Subcommittee on Oversight and Investigations.)

As a result of a commitment made by FDA to congressional oversight committees, work began on a document intended to assist medical device manufacturers in planning and implementing a preproduction quality assurance program. In the **Federal Register** of May 19, 1987 (52 FR 18747), the agency published a notice of availability of a draft document entitled "Preproduction Quality Assurance Planning; Recommendations for Medical Device Manufacturers" (Ref. 4). That document was reviewed by the Device Good Manufacturing Practices Advisory Committee and discussed at an open committee meeting held on May 4 and 5, 1988 (Transcript Docket No. 88D–0087). The agency published a notice in the **Federal Register** of October 5, 1989 (54 FR 41165), announcing the availability of the final version of the document.

ii. FDA evaluations

In January 1990, FDA published the results of an evaluation of device recalls that occurred from October 1983 through September 1989, in a report entitled "Device Recalls: A Study of Quality Problems" (Ref. 3). (See 55 FR 21108, May 22, 1990, where FDA announced the availability of the report.) FDA found that approximately 44 percent of the quality problems that had led to voluntary recall actions during this 6-year period were attributable to errors or deficiencies that had been designed into the particular devices and that may have been prevented by adequate design controls. FDA believes that this figure is unacceptable from a public health standpoint. Some of the more egregious examples that FDA found during its evaluation included: (1) The failure to properly identify and establish adequate physical and performance requirements for the device before production; (2) the failure to verify that the device met physical and performance requirements before production; (3) the failure to ensure that device components functioned properly in conjunction with other components; (4) the failure to ensure that the environment would not adversely affect components; and (5) the failure to select adequate packaging materials. These design-related defects involved both noncritical devices (e.g., patient chair lifts, in vitro diagnostics, and administration sets) and critical devices (e.g., pacemakers and ventilators). With respect to software used to operate medical devices, the data are even more alarming. A study of software-related recalls for the period FY 1983—FY 1991 indicated that over 90 percent of all software-related device failures was due to design-related errors, generally, the failure to validate software prior to routine production (Ref. 5).

iii. The Inspector General's Report

In 1990, the Department of Health and Human Services' Inspector General (IG) conducted a study entitled "FDA Medical Device Regulation From Premarket Review to Recall" (Ref. 6). The purposes of the study were to describe FDA's regulatory process for selected medical devices that had been recalled and to identify potential vulnerabilities and strengths in the FDA regulatory system for medical devices. The devices selected for the study were defibrillator/cardiac monitors, balloon catheters, spinal fixation systems, heart valves, lithotripters, balloon inflation devices, insulin infusion pumps, and ventilators. As a result of the study, the IG recommended that FDA incorporate the preproduction quality assurance recommendations into the CGMP regulations for medical devices. Indeed, one company official interviewed as part of this study recommended that preproduction quality assurance requirements be incorporated into the device CGMP regulations.

iv. Proposed Changes

As stated in proposed § 820.1, the purpose of the device CGMP regulations is to help ensure that all devices will be safe and effective and otherwise in compliance with the act. FDA believes that, except for the most simple devices, i.e., certain class I devices, there cannot be an adequate assurance of safety and effectiveness unless proper physical and performance parameters are established during the design stage; such assurance cannot be provided solely by manufacturing controls. Therefore, FDA has concluded that it is essential that those firms and individuals who design class II, class III, and certain class I medical devices discussed in more detail below do so under formal controls that will ensure that, for each intended use of a device, specifications are established and validated to be adequate and that the final design actually meets these validated specifications.

In response to the ANPRM and the November 1990 information document, both of which discussed the proposed addition of design controls, both large and small medical device manufacturers expressed support for the addition of design controls to the device CGMP regulations. For example, one multinational manufacturer of medical devices, pharmaceuticals, biologics, and veterinary medicines (Ref. 7) stated: "The inclusion of design validation in the revised Good Manufacturing Practices (GMP) regulation is a good idea which is being implemented by many device manufacturers. The degree of formally documented validation procedures varies considerably within the device industry." The president of a small manufacturer (Ref. 8) of noncritical devices with 2 years of experience in implementing the specifications for quality systems contained in ISO 9001 said:

> Our experience validates the comments expressed in the summary of the proposed rules: although the implementation can be time consuming, it is our opinion that the medical device product leaving the design phase is in fact of far higher quality than a product without the protocol. By identifying problems early in the design phase, a great deal of subsequent engineering change to an item in production is eliminated. This is probably a net saving to the manufacturer; if the protocol is followed, the development may actually be more efficient. In addition, use of ISO 9001 better equips U.S. manufacturers to compete in a world market.

Thus, in accordance with the SMDA, the agency's experiences with design-related recalls, and comments on the ANPRM and November 1990 information document, FDA is proposing to require the manufacturers

of class II, class III, and certain class I medical devices to establish and implement design controls, with the extent of the controls based on the intended use of the device. FDA welcomes comment on this proposal.

FDA is not proposing to subject the majority of class I devices to design controls because FDA does not believe that such controls are necessary to ensure that such devices are safe and effective and otherwise in compliance with the act. For most class I devices, FDA believes that the production controls in this proposed regulation and the other general controls of the act will be sufficient, as they have been in the past, to ensure safety and effectiveness. However, FDA believes that certain class I devices do raise design-related safety and effectiveness concerns. For such class I devices, the safety, effectiveness, or both, of these devices will, FDA believes, be significantly enhanced by design controls. These devices are identified in the list below. (The list indicates the classification regulation section in title 21 of the Code of Federal Regulations under which the device is listed and the generic name of the device.)

LIST OF CLASS I DEVICES SUBJECT TO CGMP DESIGN CONTROLS

21 CFR	Device
862.2050 through 862.2920.	Instruments, Clinical Laboratory.
868.6810	Catheter, Tracheobronchial Suction.
878.4460	Glove, Surgeon's.
880.4680	Apparatus, Single Patient, Portable Suction.
880.5510	Lift, Patient, Non-AC-Powered.
880.6760	Restraint, Protective.
892.1100	Camera, Scintillation (gamma).
892.1110	Camera, Positron.
892.1130	Counter, Whole Body, Nuclear.
892.1300	Scanner, Rectilinear, Nuclear.
892.1320	Probe, Uptake, Nuclear.
892.1330	Scanner, Whole Body, Nuclear.
892.1410	Synchronizer, Electrocardiograph Nuclear.
892.1970	Synchronizer, Radiographic ECG/Respirator.
892.5650	System, Applicator, Radionuclide Manual.
892.5740	Source, Radionuclide Teletherapy.

When reviewing the list of class I devices to determine whether design controls were needed to ensure the safety and effectiveness of class I devices, FDA concluded that there were two categories of class I devices that should be subject to design controls. The first of these categories consists of devices whose performance cannot be validated properly unless the design process is controlled from the outset. The second category consists of devices that have had design-related problems that have, or could have, significantly affected their safety or effectiveness and injured the user or consumer. This, FDA believes, is a clear signal that design controls are needed. (Some of the devices on the list, such as the radiological devices, fall into both categories.)

Clinical laboratory instruments, cameras, and radiological devices fall into the first category of devices. For these devices, FDA believes that design controls are necessary to ensure that performance specifications are properly established and validated as adequate prior to production. In many cases, these are computerized devices, and thus, FDA believes, proper performance can only be ensured through proper assessment of the design as it is developed during the design phase.

The remaining devices (and the radiological devices as well) fall into the second category. With regard to the suction catheter and the suction apparatus, FDA believes that design controls are necessary to ensure the strength and compatibility of materials and bonded surfaces to minimize separation of components and breakage during use, both of which have been problems in the past. FDA believes that these issues are crucial to the safety and effectiveness of these devices. Similarly, FDA believes that it is critical that the barrier characteristics of materials used in surgeon's gloves be established and proven prior to production of these gloves. With regard to patient lifts and the radiological devices, FDA believes that the specifications for mechanical load capacity, mechanical stability, and strength of materials must be established and assessed as appropriate for their intended use, prior to production, to ensure safety. For protective restraints, FDA believes that design controls are necessary to ensure proper belt design and user instructions.

B. Purchasing Controls

The quality of purchased product and services is crucial to maintaining the intrinsic safety and effectiveness of a device. Many device failures due to problems with components that result in recall are due to unacceptable components provided by suppliers (Ref. 3). FDA has found during CGMP inspections that the use of unacceptable components is often due to the failure of the manufacturer of the finished device to adequately establish and define requirements for the device's purchased components, including quality requirements. Therefore, FDA believes that the purchasing of components, finished devices, packaging, labeling, and manufacturing materials must be conducted with the same level of planning, control, and verification as internal activities.

The appropriate level of control should be achieved, FDA believes, through a proper mix of supplier and in-house controls. Purchasing contracts, orders, or other purchasing documents must clearly and unambiguously specify the necessary requirements for the product or service ordered. This means, of course, that a manufacturer must establish and validate component requirements prior to purchasing the component. (FDA expects these steps to occur during the preproduction design stage.)

Each manufacturer is also responsible for ensuring that purchased products and services conform to specifications, first, by confirming the supplier's quality system and, second, by continued monitoring of the supplier's quality systems and the quality of the items and services received. Accordingly, FDA also is proposing general requirements for manufacturers to assess the capability of suppliers to provide quality products and services, along with general requirements for ensuring that purchasing documents clearly describe the requirements for the product or service purchased.

C. Servicing Controls

FDA finds, as a result of reviewing service records, that the data resulting from the maintenance and repair of medical devices provide valuable insight into the adequacy of the performance of devices. Thus, FDA believes that service data must be included among the data manufacturers use to evaluate and monitor the adequacy of the device design, the quality system, and the manufacturing process. Accordingly, FDA is proposing to add general requirements for the maintenance of servicing records and for the review of these records by the manufacturer. Servicing controls will apply to servicing conducted or controlled by or for finished device manufacturers (e.g., conducted by a manufacturer, employee, agent, or contractor). Manufacturers must ensure that the performance data obtained as a part of servicing are fed back into the manufacturer's quality system for evaluation as part of the overall device experience data.

D. Changes in Critical Device Requirements

In the June 15, 1990, ANPRM, the agency announced that it was considering whether to combine the critical device requirements with the general requirements and modify the critical device terminology in the device CGMP regulations because of duplication of critical and noncritical device requirements and the difficulty that both FDA and industry sometimes have experienced in identifying critical components and critical operations. As a result of the comments received in response to the June 15, 1990, ANPRM and the November 1990 information document, FDA is now proposing to eliminate the critical component and critical operation terminology contained in the present CGMP requirements for devices, and to meld the duplicative requirements into the general requirements of the revised CGMP regulations for medical devices. The increased emphasis on purchasing controls and on establishing the acceptability of component suppliers, however, ensures that the intent of the present critical component requirement is carried forward into the revised CGMP. The addition of a requirement to validate and document special processes further ensures that the requirements of the present critical operation requirements are retained. Process validation is a requirement of the current CGMP and guidelines were published in 1987 to assist manufacturers in establishing process validation procedures (Ref. 9).

FDA is proposing to retain the distinction between critical and noncritical devices for one regulatory purpose. Traceability will continue to be required only for critical devices, and each manufacturer should refer to the definition of "Critical device" in determining whether the traceability requirements apply to that manufacturer's device. FDA will continue to maintain an illustrative list of critical devices to assist device manufacturers in identifying critical medical devices. A current list may be obtained from FDA's Division of Small Manufacturers Assistance (address above), telephone 1–800–638–2041. Neither the proposed nor the current list is intended to be definitive or exhaustive.

E. Overview of Modifications of Specific Requirements

FDA's experience indicates that some existing CGMP requirements for medical devices should be modified, and others clarified, to accomplish their intended purpose. Such is the case with the failure investigations requirements (§ 820.162) and with requirements for investigating device complaints pertaining to death, injury, or health hazards (§ 820.198). The intent of these provisions is to ensure that firms adequately investigate complaints and device failures in order to identify, correct, and prevent the cause of device defects. The present regulations require firms to maintain records to facilitate these activities and to allow FDA to determine compliance with current complaint investigation requirements (§ 820.198) and medical device reporting (MDR) requirements in part 803 (21 CFR part 803). However, FDA has learned through numerous CGMP inspections and investigations of device failures that firms often do not have adequate written procedures for handling complaint reporting and failure investigations. This lack of written procedures, FDA believes, results in inadequate followup which, in turn, results in device failures that could and should have been prevented. Thus, the agency believes that written procedures are necessary to manage the complaint reporting and failure investigation requirements of the device CGMP regulations and to ensure consistent performance of appropriate activities by the proper individuals.

Regarding measures established to identify and solve quality problems, FDA finds that many are structured to focus upon identifying solutions to apparent problems on the basis of immediate information. Inadequate provisions are made for collecting and correlating all salient information to determine and identify the root cause of, and all factors contributing to, a problem and to evaluate all the implications of that cause. Accordingly, the agency intends to clarify existing § 820.20 to require each manufacturer to establish a written program for evaluating all internal and external quality data for purposes of identifying quality problems that result in device defects and developing and implementing corrective action. These clarifications appear in § 820.100.

Because many changes in device components and manufacturing processes can, and do, alter the characteristics of a device and adversely affect performance and quality characteristics in a way that is not readily detectable by visual inspection or routine testing of a device, a manufacturer must be able to demonstrate (i.e., to validate by documented analysis, challenge testing, and evaluation) that the changes accomplish their purpose and have not adversely affected the safety and effectiveness of the device. FDA's recall data show that defects in devices often are caused by changes that were not properly validated (Ref. 3). Had the manufacturers complied with CGMP's, and done the validation that is necessary to establish that a proposed change does what it is supposed to do, and does it properly (without any effect on safety or effectiveness), the need for these recalls could have been avoided. Accordingly, FDA is proposing to clarify that the CGMP requirements for specifications and process changes, currently found in § 820.100(a)(2) and (b)(3), to mandate that device specification and process changes be validated before implementation and that the results of these activities must be recorded.

F. Harmonization

FDA is proposing to reorganize the structure of the device CGMP regulations and modify some of their language in order to harmonize them with international quality standards. Thus, FDA is proposing to relocate and combine certain requirements to better harmonize the requirements with specifications for quality systems in the ISO 9001 quality standard and to use as much common language as possible to enhance conformance with ISO 9001 terminology.

The EC intends to harmonize all marketing requirements for products and services sold in the EC countries to ensure free trade among these countries. This action will effectively create a huge common market of over 320 million people. Medical devices are one of the product categories for which marketing requirements will be harmonized. Harmonization of device requirements within the EC will be accomplished through the issuance of directives that specify the essential requirements that must be met in order to market devices in the EC. Both horizontal standards, applicable to broad categories of products, and vertical standards, which are product specific, will be used in demonstrating conformity with the requirements of the directives. Harmonized quality systems or good manufacturing practice requirements are among the horizontal standards that will be applicable to medical devices.

Two European Standards, EN46001 "Quality Systems—Medical Devices—Particular Requirements for the Application of EN29001" (Ref. 10) and EN46002 "Quality Systems—Medical Devices—Particular Requirements for the Application of EN29002" (Ref. 11) have been prepared by the Joint European Committee for

Standardization/European Committee for Electro-technical Standardization Coordinating Work Group on Quality Supplements. EN46001 will be applicable to those manufacturers subject to design controls who choose to comply with a total quality system that want to market devices in the EC. EN46002 will be applicable to those manufacturers who choose to comply with a production quality system.

EN46001 consists of ISO 9001 requirements plus supplemental requirements specific to medical devices. The revised CGMP regulations will incorporate the requirements of ISO 9001 plus supplemental requirements specific to medical devices that are found in the present CGMP regulations. FDA is working closely with EC officials to harmonize the supplemental requirements of this proposed revised CGMP regulations with those of EN46001.

At a public meeting held on June 19 and 20, 1990 (55 FR 17502), FDA first discussed the possibility of harmonizing the device CGMP regulations with international quality standards with the agency's Device Good Manufacturing Practice Advisory Committee. Subsequently, at an open meeting of the Device Good Manufacturing Practice Advisory Committee held on May 29, 1991 (56 FR 15626), FDA proposed to facilitate harmonization by adopting verbatim the specifications in the ISO 9001 quality standard and to add supplements as necessary to achieve CGMP regulations appropriate for medical devices. However, FDA did not receive the expected permission to reprint for general distribution to the public either the ISO 9001 document or the ISO companion document containing the definitions of quality terms, ISO 8402 (Ref. 12). Of course, FDA would have to publish the documents in the **Federal Register** in order to propose to adopt them as binding regulations under the Administrative Procedure Act (5 U.S.C. 553). Furthermore, FDA decided, upon further reflection, that much of the language of ISO 9001 would need to be adapted for inclusion in the revised CGMP regulations for medical devices.

Therefore, FDA has determined that the most appropriate approach to developing device CGMP regulations equivalent to the quality system specifications in ISO 9001 is to structure the revised CGMP regulations as closely as possible to ISO 9001 specifications and to use similar terminology where appropriate.

FDA believes that revising the device CGMP regulations so they are comparable to the ISO 9001 specifications for quality systems will, once harmonization is achieved, reduce a source of competitive disadvantage to U.S. manufacturers attempting to market devices in the EC. Harmonization of FDA's device CGMP regulations with the medical device good manufacturing practice rules of the EC, and with comparable device good manufacturing practice rules being developed by Canada and Japan, will minimize the number of quality systems with which the U.S. industry must comply to compete in the international market. Harmonization is intended to increase the likelihood that manufacturers need to develop only one quality system for their primary markets. Also, unless FDA's device CGMP regulations are comparable to the EC's harmonized good manufacturing practice standards, FDA will have difficulty establishing mutual CGMP inspection agreements with other countries.

Finally, by requiring all manufacturers to design and manufacture devices under the controls of a total quality system, FDA believes that the proposed changes in the CGMP regulations will improve the quality of medical devices manufactured in the United States for domestic distribution or exportation as well as devices imported from other countries and, thus, are necessary to ensure that only safe and effective devices are distributed in conformance with the act. Thus, harmonization is not intended to, and should not be viewed as, lowering or lessening CGMP requirements. Rather, harmonization means a general enhancement of CGMP requirements among the world's leading producers of medical devices.

III. The Agency's Tentative Conclusions on the Public Comments

A. Comments on the June 15, 1990, ANPRM

As noted previously, FDA published an ANPRM (55 FR 24544, June 15, 1990) which announced that FDA was considering whether the agency should propose to revise the CGMP regulations for medical devices in part 820. At that time, the agency said that the decision to revise the device CGMP regulations would be based on the information and comments submitted in response to the notice; the recommendations of the Device Good Manufacturing Practice Advisory Committee; analysis of FDA's device recall data; the agency's experience in applying the device CGMP requirements in its regulation of medical devices; and the development of harmonized good manufacturing practice regulations by the EC.

In response to the ANPRM, FDA received 53 comments concerning changes to the device CGMP regulations, including comments from industry associations and from medical device manufacturers representing a broad section of small and large firms that manufacture both critical and noncritical devices ranging from the relatively simple to the extremely complex. The general comments covered a wide variety of concerns, from expressing support for implementing practices that would improve the industry's record for design quality, to expressing opposition to design controls. Comments also discussed the elimination of the critical device requirements, harmonization, and reciprocity.

i. Harmonization

1. Several comments said that Congress did not intend for FDA to ensure that manufacturers are competitive in the world marketplace and questioned FDA's legislative authority to undertake harmonization. It was stated that manufacturers and distributors should be responsible for proving compliance with international quality standards, if they wish to export, without Government intervention.

FDA believes the SMDA addresses an important aspect of the agency's role in encouraging the international harmonization of good manufacturing practices. Section 803(a) of the SMDA specifically directs the agency, in entering into agreements with foreign countries to facilitate commerce in devices, to encourage the mutual recognition of good manufacturing practice regulations under section 520(f) of the act, as well as other regulations and testing protocols as necessary. Further, section 514(a) of the act (21 U.S.C. 360d(a) encourages FDA to consult with internationally recognized standard setting organizations when issuing performance standards. FDA does, therefore, have a specific charge from Congress to promote international harmonization of good manufacturing practices. Such a charge is in addition to the agency's authority generally to strive toward harmonization that is consistent with legal requirements.

In this area, harmonization does much more than promote the competitiveness of U.S. device manufacturers; because ISO 9001 promotes a more comprehensive quality assurance system than FDA's present CGMP requirements, FDA believes that this rulemaking will also mean that safer, more effective medical devices are available in the United States. FDA's primary goal in revising the device

CGMP regulations and harmonizing with ISO 9001 is to strengthen its regulations. Thus, FDA would pursue the proposed changes regardless of the progress of the EC's activity to develop harmonized good manufacturing practice standards. Although harmonization with the EC's efforts in this area is secondary, FDA believes it will have significant competitive advantages for the U.S. medical device industry.

2. Several comments questioned FDA's reliance on recall data and whether the changes prompted by FDA analysis of this data would result in the desired corrections and address the quality problems with medical devices.

FDA's recall data are derived from the investigation and resolution of actual medical device failures. Because the recall data relate to actual device failure, FDA believes the data are appropriate for establishing the causes of device failures. The proposed revision of CGMP requirements will require each manufacturer to establish and implement a total quality system appropriate to the device manufactured. The benefits of such quality systems are well established (Ref. 13), and they have also been attested to by manufacturers who have successfully implemented such systems. (See section II.A. of this document.)

In response to the need to provide an economic impact analysis of the proposed CGMP revision, FDA commissioned an independent contractor, the Eastern Research Group, Inc. (ERG), to conduct the analysis (Ref. 14). The contractor's report also supports the public health need for revising the current rules. ERG analyzed FDA's recall and MDR data, interviewed device manufacturers and consultants, and concluded that, because a substantial portion of design problems result from preventable errors or foreseeable design shortcomings spawned by poor design practices, the proposed regulations will improve design practices for a major portion of the industry and thus eliminate a substantial portion of medical device design problems. ERG estimates that, if the proposed design controls are implemented, up to 73 percent of design-related recalls could be avoided. Based on this assumption, ERG estimates that the proposed CGMP regulations would prevent one-third of the design-related problems, avoiding 53 deaths and 1,257 injuries per year. The medical device industry would gain substantial economic benefits from the proposed changes to the CGMP regulations in three ways: cost savings from fewer recalls, productivity gains from improved designs, and efficiency gains for export-oriented manufacturers, who would now need to comply with only one set of quality standards. ERG has estimated that the savings to industry from avoided design-related recalls could be in the tens of millions of dollars.

3. Other comments noted that FDA should not surrender its inspection activity to other countries and that mutual inspection agreements should be pursued with caution.

Because of FDA's limited resources, FDA welcomes opportunities for establishing inspection agreements with other countries, where inspections by the other countries may augment or replace FDA inspections. However, FDA does not enter into such agreements lightly. The adequacy of the foreign country's inspection force, training programs, reporting, and enforcement are all carefully considered and evaluated before FDA enters into such agreements, and FDA preserves its ability to conduct audits.

4. Several comments suggested that FDA issue a guideline, rather than new regulations, to address the changes, while others opposed extending CGMP requirements to devices that are presently exempt.

Guidelines are not binding legal requirements. FDA's experience with guidelines has shown that many manufacturers do not adopt guidelines because they are not mandatory. FDA believes that the proposed changes must be followed to provide adequate assurance that devices are safe and effective. Because experience shows that voluntary guidelines would not be uniformly followed, FDA believes that the changes in the device CGMP regulations must be mandatory requirements.

As for the scope of the requirements, the proposed revised CGMP requirements will apply, as do the present ones, to manufacturers of finished devices distributed in the United States, unless specifically exempt by regulation. Those manufacturers now exempt from the devices' CGMP regulations would also be exempt from the revised CGMP regulations. Moreover, some CGMP requirements may not be applicable to all device manufacturers. For example, those manufacturers which do not produce serviceable devices or devices requiring installation would not be subject to the proposed CGMP regulations that pertain to such devices. Each manufacturer must develop a quality system that is appropriate for each particular device and its design, manufacture, and production processes. FDA will continue to evaluate the adequacy of each manufacturer's quality system and conformance to the selected system during good manufacturing practice inspections.

5. Several comments objected to the elimination of the two-tier system and critical device list associated with the present device CGMP regulations.

FDA believes that experience has shown the need to apply to medical devices generally some of the requirements currently applicable only to critical devices. As discussed earlier, the critical device list will be retained for traceability purposes. FDA welcomes further comment on this proposal.

6. Several of the comments on the proposed addition of design controls to the device CGMP regulations focused on increased costs to small U.S. manufacturers. Comments also claimed that the addition of design controls will slow the introduction of new products. Some comments noted that design concerns should be addressed during FDA's market clearance processes involving premarket notifications for devices, submitted under section 510(k) of the act (21 U.S.C. 360(k)) (510(k) or premarket notifications) and premarket approval applications (PMA's), submitted under section 515 of the act (21 U.S.C. 360e).

Medical device establishments will incur compliance costs in extending their quality systems to meet the proposed FDA regulation. However, FDA believes there is ample evidence to suggest that the long-term benefits will outweigh the costs. As stated previously, these estimated costs and benefits of design controls are contained in the economic impact analysis commissioned by FDA under contract No. 223–91–8100 (Ref. 14).

Moreover, FDA believes, based on comments submitted in response to the ANPRM, that both large and small manufacturers can realize cost and time savings through the proper establishment and implementation of appropriate design controls. (See section II.A. and comment 2 of this document.) In addition, a May 1991 study by the U.S. General Accounting Office indicates that both large and small manufacturers who developed quality improvement programs realized reduced times to develop new products, as well as reduced product defects (Ref. 13), which should result both in reduced costs and increased customer satisfaction.

FDA recognizes that the device industry consists of manufacturers of devices whose design requirements vary significantly based on the intended use of the device. The proposed regulation

sets out the general design control requirements. Under the proposed regulation, each manufacturer is required to develop a detailed design plan for each device it manufactures if it is a class II, class III, or designated class I device and an operating procedure that implements the plan. Device manufacturers are responsible for ensuring that the design plans and operating procedures establish all controls necessary to ensure the production of a safe and effective device. The type of the design controls established and the precise details of implementation are left for each manufacturer to decide, based on the complexity and intended use of the device. FDA will examine these design plans and operating procedures during inspections to determine whether a manufacturer is complying with the device CGMP regulations.

With respect to FDA's market clearance processes, only about 3 percent of all medical devices are subject to premarket approval, and premarket approval requirements do not address all of the design control elements envisioned for the revised CGMP. Further, design controls are not typically evaluated as part of a 510(k) submission.

Many of the comments which the agency received concerning its intention to consider revising the device CGMP regulations pertained to suggested changes and suggested language that were included in the November 1990 information document. These comments are summarized in the following section and discussed in detail in section IV. of this document.

ii. Comments on the November 1990 Information Document

In November 1990, FDA announced the availability of the November 1990 information document (Ref. 2). This document was developed in response to the recommendation, made by the agency's Device Good Manufacturing Practice Advisory Committee during its June 19 and 20, 1990, committee meeting (55 FR 17502), that FDA collaborate with industry in developing language for proposed revisions to the CGMP regulations. The November 1990 information document contained suggested changes and additions to the device CGMP regulations and was mailed to all registered medical device manufacturers to obtain comment and facilitate discussion of the changes being considered by FDA. In response to the November 1990 information document, FDA received 42 letters containing comments on the suggested changes. Letters were received from 10 industry associations (including 1 Canadian and 1 European industry association), 22 manufacturers (both large and small), 2 consulting firms, 2 associations representing medical device users, and members of the agency's Device Good Manufacturing Practice Advisory Committee.

Most of the comments concerned the proposed addition of design controls to the device CGMP regulations, the proposed adoption of CGMP regulations that conform with ISO 9001 specifications for quality systems, and the proposal to modify the critical device requirements and meld the requirements into the general CGMP requirements. The majority of the comments indicated that industry now supports the conformity of FDA's device CGMP regulations with appropriate specifications of ISO 9001 and the harmonization of FDA's device CGMP regulations with the EC's good manufacturing practice requirements for medical devices, EN46001, which is based on ISO 9001.

Approximately one-third of the letters specifically expressed support for the addition of design controls. Others suggested changes in the language proposed for design controls. However, concerns were expressed about retrospective design requirements, the economic impact of design controls, the availability of design data at the manufacturing facility, and the availability of proprietary or trade secret information.

FDA welcomes comments on the proposal to apply design controls to all class III and class II and certain class I devices and on FDA's proposal to make the revised regulations effective 180 days after the date of publication of the final revised regulations. At that time all manufacturers will be expected to have design controls established and implemented. Design control requirements will not be retroactive, although they will apply to design changes made after the effective date to currently marketed products.

All documents required by the CGMP regulations must be maintained at the manufacturing site or other location that is reasonably accessible to FDA. If reasonably accessible (i.e., capable of being provided during the course of an inspection), design control records may be maintained at a facility other than the manufacturing facility, e.g., the research and development (R&D) facility.

The handling of confidential documents is addressed similarly in the current CGMP regulations in § 820.180 and in the proposed revision of § 820.180. Trade secret information is protected by provisions of 21 CFR part 20, which exempts from public disclosure trade secrets and commercial or financial information that are privileged or confidential. In addition, section 301(j) of the act (21 U.S.C. 331(j)) prohibits the release of trade secret information except as set forth in that provision.

The economic impact of design controls was addressed above in comment 2 of section III.A. of this document and is addressed in detail in the economic impact analysis report (Ref. 14).

Pertinent comments received in response to the November 1990 information document are addressed in section IV. of this document.

IV. Analysis of Revised CGMP Regulation for Medical Devices

Following is a description of the proposed revision of the CGMP regulation for medical devices and response to comments received in response to the June 15, 1990, ANPRM and the November 1990 information document. For each section of the proposed revision, references to the applicable section of the November 1990 information document and the requirements of ISO 9001 that have been incorporated into the proposed CGMP regulation are provided. Many of the comments resulted in changes in the language of the proposed regulation.

A. General Provisions (Subpart A)

i. Scope

The scope of the proposed CGMP regulation is described in proposed § 820.1. It will apply to methods used in, and the facilities and controls used for, the design, purchasing, manufacture, packaging, labeling, storage, installation, and servicing of finished devices intended for human use. This is consistent with the scope of ISO 9001. The regulation would not apply to manufacturers of components which are not manufactured specifically for medical devices. However, device manufacturers must assess the quality systems of their suppliers and otherwise ensure that "off-the-shelf" components meet their specifications under proposed § 820.50.

ii. Definitions

Comments on the November 1990 information document recommended adding a number of terms. Those which were pertinent to the proposed changes were added to proposed § 820.3. Terms presently defined in the CGMP regulation that are omitted from proposed § 820.3 because the proposed revisions render them unnecessary are:

Critical component, critical operation, noncritical device, and quality assurance.

Definitions being added to proposed § 820.3 are: Complaint, design history record, design input, design output, design review, establish, executive management, lot or batch, nonconforming, production, quality, quality policy, quality system, record, reprocessing, servicing, special process, specifications, validation, and verification.

Design review, nonconforming, quality, quality policy, and quality system are definitions taken from, or are modifications of, definitions contained in ISO 8402—"Quality vocabulary" (Ref. 12). The November 1990 information document suggested a modification in the term "quality assurance" to include the entire life cycle of a device. In the proposed CGMP regulation, the term "quality assurance" has been deleted and replaced with "quality system," which applies to the entire life cycle of a device. "Executive management" is defined to make it clear which employees are executive management. "Establish" is terminology from ISO 9001. To avoid confusion concerning what is involved when the proposed regulations require manufacturers to establish something, FDA has defined it to include defining, documenting, and implementing. "Record" is defined to make clear that all documents are records for inspectional and recordkeeping purposes. The remaining definitions are taken from the current FDA CGMP regulations or are modifications of definitions taken from other sources.

FDA is also proposing to modify the existing definitions of a number of terms. The existing definition of "component" in proposed § 820.3(c) is modified to clarify that software, firmware, labeling, and packaging are subject to component controls. The definition of "control number" in proposed § 820.3(d) now includes purchasing to indicate that the history of purchasing is a part of traceability. "Critical device" is defined in proposed § 820.3(e) in terms of serious injury, rather than significant injury, to conform with concepts in other FDA regulations, e.g., the Medical Device Reporting (MDR) regulations in part 803. The definition of "Device Master Record" has been expanded to include purchasing, servicing, and installation records. The definition of "finished device" is clarified in proposed § 820.3(l) to include a device that is intended to be sterile, but that is not yet sterilized. In proposed § 820.3(n), the definition of "manufacturer" is revised to include designers, contract sterilizers, specification developers, and initial distributors of imported devices. Ethylene oxide or other sterilant residues are added to proposed § 820.3(o) definition of "manufacturing material." The term "quality audit" in proposed § 820.3(s) replaces the term "audit" in existing § 820.3(b) and the definition has been revised to harmonize with ISO 8402.

7. Several comments on the November 1990 information document suggested a definition for "quality." The proposed definition of "quality" in proposed § 820.3(r) takes into consideration the comments received and has been modified to emphasize that quality means the totality of safety and performance attributes and characteristics that satisfy fitness-for-use.

8. Other comments addressed the need for a definition of the term "signature" to allow for kinds of electronic or computerized signatures or identification in lieu of a written signature. The agency is currently studying whether to adopt a definition of electronic signatures for all regulated industries that includes electronic or computerized identification, and has issued an ANPRM on this issue (57 FR 32185, July 21, 1992).

iii. Quality system

FDA is proposing to revise § 820.5. This section of the proposed CGMP regulation incorporates ISO 9001 4.2 "Quality system." The term "quality system" is used to define a more comprehensive quality program than presently required on the existing CGMP regulations, taking into account the addition of design, purchasing, and servicing controls to the CGMP regulation. No comments were received on the similar language in the November 1990 information document.

B. Quality System Requirements (Subpart B)

i. Management responsibility

FDA is proposing to revise § 820.20. The proposed requirements revise the current requirements in existing § 820.20 to emphasize executive management's responsibility for ensuring that an adequate quality system is established and implemented. This section incorporates the requirements of ISO 9001 4.1 "Management responsibility."

Suggested language for proposed § 820.20 was included in the November 1990 information document. Comments received are addressed below.

Proposed § 820.20(a) requires each manufacturer's executive management to establish the firm's quality policy and objectives. Suggested language for this proposed section was included in the November 1990 information document. This section incorporates the requirements of ISO 9001 4.1.1 "Quality policy." Proposed § 820.20(a) requires the top or executive management of each manufacturer to ensure that the firm's quality policies and objectives are defined, documented, implemented, maintained, and communicated to all employees whose work or responsibilities may affect quality. Quality policy is defined in proposed § 820.3(v).

Executive management has the ultimate responsibility for ensuring that devices produced and distributed are safe and effective. Moreover, executive management's commitment to the quality system and the communication of that commitment to all employees is crucial to the success of the quality system (Ref. 13). FDA's experience indicates that, without such commitment by management and without continuous reinforcement of this management's commitment, employees over time stop adhering to quality system requirements, and the effectiveness of the program erodes. For example, while FDA's CGMP inspection results reveal that most device manufacturers have documented good manufacturing practice programs, because of a lack of executive management's commitment to the program, or a failure to communicate that commitment to employees in practical terms, these programs sometimes are not followed.

9. Several comments in response to the November 1990 information document stated that it was not appropriate to make the understanding, implementation, and maintenance of a quality policy a regulatory requirement and to make executive management responsible for implementation.

FDA disagrees with these comments. Executive management has the ultimate responsibility for ensuring the quality of all devices distributed. Therefore, it is appropriate for executive management to set the pace by establishing the quality policy and maintaining the company's commitment thereto. A critical feature of any successful quality system is executive management's role in providing leadership to the quality program (Ref. 13). Executive management must lead the process, demonstrating a commitment to quality through their daily actions and working to build quality values throughout the organization. FDA believes that through training and continuous reinforcement of the importance of the quality policy

by executive management, employees' understanding of the quality policy can be achieved.

The proposed amendment to § 820.20(b) clarifies that the responsibility and authority for the quality system must be defined and documented and provides examples of quality system activities for which responsibility and authority must be established. This section also establishes general verification requirements and a requirement that manufacturers appoint a management representative with authority over and responsibility for the quality system.Suggested language for this section was contained in the November 1990 information document but has been revised. Therefore, many of the comments no longer apply to the language now proposed for the section. This section of the proposed CGMP regulation incorporates ISO 9001 4.1.2 "Organization."

10. Several comments on similar language that was included in the November 1990 information document complained that the requirement (in proposed § 820.20(b)(3)) for a single individual to manage the quality system at the management level would be too restrictive.

FDA disagrees with these comments. FDA believes it is imperative that one management representative with overall authority be assigned responsibility for the quality system and have access to all parts of the quality system. Responsibility and authority must be established at the top management level to ensure that quality problems are resolved by a person with the ability and authority to implement and oversee a quality control system.

11. One comment asked if the management representative can also be responsible for other activities.

The management representative may carry out the proposed responsibility, either separately or in conjunction with other functions and responsibilities, as long as management effectiveness is not diminished and there is no conflict of interest.

Proposed § 820.20(c) requires each firm to assign a management representative with executive authority to periodically review the quality system to ensure its continuing suitability and effectiveness. An important part of this review is the review of the quality audit results. However, management review responsibilities extend beyond review of audit results and include all aspects of the quality system.

Proposed language for this section was not included in the November 1990 information document. This section incorporates the requirements of ISO 9001 4.1.3 "Management review."

ii. Quality audit

FDA is proposing to retain in proposed § 820.22 the current CGMP requirements of § 820.20(b), but it is proposing to change the title of this section from "Audit procedures" to "Quality audit" to be consistent with ISO 9001 and better identify the function. The term "quality assurance program" is replaced with "quality system" wherever it appears. Also this section states that reports written to document the audit of suppliers and contractors are subject to FDA review and copying. FDA needs access to these reports to determine compliance with proposed § 820.50. Proposed § 820.22 contains the requirements of ISO 9001 4.17 "Internal quality audits."

iii. Personnel

FDA is proposing to redesignate the requirements of CGMP § 820.25(b) to proposed § 820.70(d) because the health condition and hygiene of employees are most pertinent to the production process.

The general requirements of existing § 820.25 on personnel and the current requirements of existing § 820.25(a) on personnel training are being incorporated into proposed § 820.25. FDA notes that training must be more than just an administrative activity. A quality system is no more effective than the people who manage and conduct the quality system activities. Therefore, training must be continuous and appropriate for each employee's current job function.

Since the proposed requirements of this section are existing CGMP requirements, the suggested language for proposed § 820.25 was not included in the November 1990 information document. Proposed § 820.25 incorporates the requirements of ISO 9001 4.18 "Training."

In addition, FDA is proposing a new requirement relating to consultants. Over the years, FDA has observed that a surprising number of firms hire consultants who have no particular expertise in the area in which the firm is seeking assistance. Proposed § 820.25(c) addresses this problem by ensuring that a consultant's fitness for the specific tasks for which he or she is retained is considered and documented.

C. Design Controls (Subpart C)

To implement the design validation provisions of the SMDA, FDA is proposing, in proposed § 820.30, to adopt, as much as practical, the language of ISO 9001 4.4 "Design control." Suggested language for this section was included in the November 1990 information document. As discussed previously in more detail and as set forth in proposed § 820.30, FDA is proposing to apply design controls to all class III and class II devices and certain class I devices.

The quality of a device is strongly influenced by decisions made during the design process. Design deficiencies will affect all devices produced and are progressively more expensive to correct as development proceeds (Ref. 4). Therefore, from both cost and safety standpoints, FDA believes it is essential that a disciplined design program be followed that will minimize the possibility of error and allow design deficiencies to be detected and corrected as early as possible.

To satisfy the proposed design control requirements, each manufacturer will be required to establish a formal, documented program to ensure that design requirements are properly established, verified, and translated into design specifications, and that the design released to production meets the approved design specifications.

12. Two comments on this section said that "Preproduction quality assurance" should be changed to "Design control," as used in ISO 9001.

FDA has retitled the section "Design Controls" and has rewritten the requirements to more closely align them with the specifications of ISO 9001.

The language contained in the information document for proposed § 820.30 has been simplified and incorporates the requirements of ISO 9001 4.4.1 "General."

13. Several comments received in response to the November 1990 information document expressed concern that the costs of implementing design validation would place small manufacturers at a competitive disadvantage.

FDA believes that manufacturers of all sizes benefit from adequate design controls. Under section III.A. and comment 2 of this document, the agency discusses the reduced costs, time savings, international compliance, and other benefits derivable from design controls. An analysis of the cost of implementing design controls for large and small manufacturers is also provided in the report entitled "Economic Analysis of Proposed Revisions to the Good Manufacturing Practices Regulation for Medical Devices" (Ref. 14).

14. Several comments expressed concern that FDA would not have the ability to separate the evaluation of the

design process from the actual device design during good manufacturing practice inspections.

During CGMP inspections, the FDA investigator will review each manufacturer's design plan and the program that each manufacturer establishes to satisfy the applicable CGMP regulation design control requirements. The investigator will evaluate both the adequacy of the methods and procedures and each firm's compliance with these methods and procedures. Normally, the investigator will evaluate the process used to establish, evaluate, and release the finished design, rather than evaluate the adequacy of the design. However, if evidence of unsafe or ineffective designs is detected during good manufacturing practice inspections, the FDA investigator has an obligation under the act to investigate.

Proposed § 820.30(b) incorporates the requirements of ISO 9001 4.4.2 "Design and development planning," 4.4.2.1 "Activity assignment," and 4.4.2.2 "Organizational and technical interfaces." Many comments received on this section of the information document no longer apply, because the proposed requirements are a major revision of the suggested language. Pertinent comments are discussed below.

Proposed § 820.30(b) requires each manufacturer to establish a written plan that is appropriate to the design, that defines each design activity, including design verification points and methods, and that identifies the person responsible for each activity. The success of any activity is dependent upon knowing what is to be done. Therefore, the design process and its interface with other internal and external organizational groups must be defined as much as possible before the design process begins. Effective planning includes consideration of production needs, e.g., production environment and equipment, workmanship requirements, process development, and validation.

Proposed § 820.30(b) also requires each manufacturer to assign to designated individuals the responsibility, and provide these individuals with sufficient authority, to carry out the required design control activities. These individuals must be qualified to carry out their assigned activities and must be provided with sufficient and adequate resources to carry out the assigned activities.

In some firms, individuals outside the design unit may participate in the design program. When the design activity involves organizations or groups in addition to the design unit, organizational and technical interface controls must be in place to ensure that needed information and data are transferred in a timely and systematic manner. Determinations that provide the basis for such controls, which should be made during the planning stage, include: What information is to be transmitted; by whom, to whom, and by what means the information is to be transmitted; and what review process is to be followed and what records are to be maintained for the information that is to be transmitted.

Proposed § 820.30(c) has been retitled "Design input" in response to comments. The language provided in the information document for this section has been substantially simplified. Proposed § 820.30(c) requires manufacturers to establish controls to ensure the design requirements are properly established. This section incorporates the language of ISO 9001 4.4 "Design input," and also specifies that the needs of the user must be reflected in the design requirements.

Design input is the design definition phase, or the design requirements definition phase, in which the design's physical and performance features or characteristics are defined. The design input is typically configured in the form of a description of all pertinent design requirements, such as physical, functional, environmental, safety, and regulatory requirements. This phase also includes the identification of components that require development and/or analysis.

FDA notes that the establishment of labeling requirements is an important element of design input. When establishing the design and labeling requirements, a manufacturer must consider a variety of factors, including the safety needs of the users (e.g., operators and patients), the environment in which the device will be used (e.g., in the home, by a health care professional, in an operating suite, in an emergency vehicle), reliability, safeguards against misuse, and, where applicable, maintainability and serviceability. Adequate maintenance instructions must be provided, so that the user can maintain the device's safety and effectiveness. To ensure manufacturability, this phase should also include the establishment of manufacturing requirements. To ensure that conformance to specifications can be determined, this phase should include quality control requirements.

15. Several comments stated that the terms "Safety and effectiveness" should be deleted in favor of "Performance" because current investigational device exemption and PMA regulations adequately address safety and effectiveness. The comments maintained that FDA is prohibited from evaluating safety and effectiveness as part of any CGMP requirement dealing with design controls because the language of section 18 of the SMDA, which added design validation to the provisions of section 520(f)(1)(A) of the act, contained an exclusion that stated "preproduction design validation (including a process to assess the performance * * * but not including an evaluation of the safety or effectiveness of a device.)"

In response to these comments, the terms "safety and effectiveness" have been deleted and replaced with "intended use of the device." However, FDA notes that the CGMP requirements are, after all, intended "to assure that [a] device will be safe and effective and otherwise in compliance with [the act]" (section 520(f)(1)(A) of the act) and that the statutory basis for the CGMP requirements is not restricted to section 520(f) but encompasses other provisions concerned with safety and effectiveness, e.g., section 515 of the act.

Moreover, because issues of safety and effectiveness affect a device's ability to perform its intended use, FDA's focus upon the process used to design and assess device performance does not relieve a manufacturer of the responsibility of establishing and maintaining controls that set and assess the proper level of safety and effectiveness of the design. Manufacturers must establish the level of safety and effectiveness that is commensurate with the intended use of the device and ensure that the design adequately reflects these needs before it is released to production. FDA will evaluate the adequacy of the controls that manufacturers have established to ensure safety and effectiveness during good manufacturing practice inspections.

16. In responding to the November 1990 information document, several comments said that the words "ambiguous" and "incomplete" should be deleted from the language suggested for the design requirement that specified, "All incomplete, ambiguous, or conflicting design requirements should be resolved * * *." These terms have been deleted because FDA determined they added nothing to the requirements. FDA intends that manufacturers should comprehensively document design requirements. In accordance with recognized quality assurance principles, FDA expects

design specifications to be complete, clear, and consistent (Ref. 4).

Proposed § 820.30(d) will require manufacturers to conduct design verification procedures appropriate to the intended use of the device. The suggested language contained in the November 1990 information document for this section has been revised. Verification methods may vary and include, among other things, hazard analysis, failure mode effects analysis, and performance testing. The frequency and extent of the assessments are left for each manufacturer to decide, but should be based on such factors as: The intended use of the finished device, its complexity, the extent of innovation and new technology introduced, and the degree of standardization. Verification must include ensuring the design is adequate for its intended use. This includes, where applicable, software validation and hazard analysis. Each manufacturer should establish a design process hierarchy and assess the acceptability of the design, both during the stages of design development and before the design is released to production. A design review should be performed at the conclusion of each stage to evaluate the design requirements and the capability of the design to meet the design requirements and to identify problems and propose solutions.

Proposed § 820.30(f) requires manufacturers to document the design output and ensure the output meets approved design requirements. Proposed § 820.30(f) was included in the November 1990 information document. The proposed requirement incorporates the requirements of ISO 9001 4.4.4 "Design output." Design output occurs at various phases in the design process, and the proposed design output requirements are intended to apply to all phases of the design process. The final design output is the product of the design process and typically consists of the final component, manufacturing material, and device specifications and drawings as well as all instructions, software, and procedures that are used for purchasing, production, installation, maintenance, and servicing. These documents are included in the device master record.

Proposed 820.30(g) is a supplement to ISO 9001 requirements. Under proposed § 820.30(d)(3), before devices are released for routine distribution, finished devices must be sampled from the first three production runs and tested for performance under actual conditions of use or simulated use conditions in the environment or simulated environment in which the device is expected to be used. FDA considers this a critical element of the validation of the manufacturing process. The requirement to conduct simulated use testing of finished devices is presently found in § 820.160 of the CGMP regulation as part of finished device inspections and is being moved to proposed § 820.30(d)(3) because FDA believes that simulated use testing at this point is more effective in ensuring that only safe and effective devices are produced. Manufacturers must also conduct such tests when they make changes that could affect safety or effectiveness in the device design or the manufacturing processes. The extent of the testing conducted should be governed by the risk(s) the device will present if it fails. FDA considers these procedures essential for ensuring that the manufacturing process does not adversely affect the device (Ref. 9).

Manufacturers may not use prototypes developed in the laboratory or machine shop as test units to meet these requirements. Prototypes may differ from the finished production devices. During research and development, conditions are typically better controlled and personnel more knowledgeable about what needs to be done and how to do it than are regular production personnel. When going from laboratory to scaled-up production, standards, methods, and procedures may not be properly transferred or additional manufacturing processes may be added. Often, changes not reflected in the prototype are made in the product to facilitate the manufacturing process. Proper testing of devices that are produced using the same methods and procedures as those to be used in routine production will prevent the distribution and subsequent recall of many unacceptable medical devices.

17. One comment said that the phrase "before releasing a design to production" in the November 1990 information document under "Design verification" should be deleted. This phrase has been deleted in proposed § 820.30(d) in response to the comment and replaced with the language in proposed § 820.30(g).

18. Several comments objected to use of the term "worst-case conditions" in the November 1990 information document. The term has been deleted in response to the comments.

19. One comment stated that the design verification wording implies that no production can take place until every process and piece of equipment is in the final form anticipated for full-scale production. In response, the wording of the proposed requirements for simulated use testing has been changed to require sampling and testing of the first three production runs. However, samples must be taken from devices that were produced using the same specifications, production and quality system methods, procedures and equipment that will be used for routine production.

20. One comment stated that design "requirements" should be changed to design "specifications." In drafting the revisions to the CGMP regulation, FDA has adopted the definitions for specifications contained in the November 1990 information document, ISO 8402 "Quality vocabulary" (Ref. 12). A specification is a document that contains requirements. Requirements thus make up a specification. The design "specifications" contain the "requirements" for the design. In this respect, FDA has deleted use of the term "requirement" in favor of specifications, and has defined "Specifications" in proposed § 820.3(bb).

Proposed 820.30(h) is a supplement to the ISO 9001 requirements. Under proposed § 820.30(h) a designated individual must be responsible for approving the release of the design to production.

The requirements of proposed § 820.30(i) incorporate the requirements of ISO 9001 4.4.6 "Design changes." Proposed § 820.30(i) was included in the November 1990 information document. It requires manufacturers to document changes made to the design specifications during the design phase and ensure that changes are adequate for their intended use.

21. Several comments said that maintaining records of design changes would be unduly burdensome.

FDA recognizes that many design changes are made during the design process, but that not all become part of the final approved design. Manufacturers are not expected to maintain records of all changes proposed during the very early stages of the design process. However, all design changes made after design review that are approved for incorporation into the design, and those changes made to correct design deficiencies, must be documented. The records of these changes create a history of the evolution of the design, which can be invaluable for failure investigation and for facilitating the design of future similar products. Such records can prevent the repetition of errors and the development of unsafe or ineffective designs.

22. Several comments suggested that the reference to clinical evaluations under "Design changes," as contained in the November 1990 information document, was unnecessary and should

be deleted. FDA has deleted the reference to clinical evaluations in response to these comments.

23. One comment recommended that any reference to change should be eliminated and the focus should be on the validation of the final, full-scale, production design. Any changes after that time would require documentation.

FDA disagrees. The safety and effectiveness of devices cannot be proven by final inspection or testing. Product development is inherently an evolutionary process. While change is a healthy and necessary part of product development, quality can be ensured only if change is controlled and documented throughout the development process. Each manufacturer must establish criteria for evaluating changes to ensure that the changes are appropriate for its designs.

Proposed § 820.30(j) requires manufacturers to maintain a record that contains the complete design history of a device. The proposed requirement to maintain a design history record is a new requirement that, although not specified by ISO 9001, is necessary so that manufacturers can exercise control and accountability over the design process and thereby maximize the probability that the final design conforms to the design specifications.

D. Document Controls (Subpart D)

Proposed § 820.40 is a revision and clarification of existing § 820.100. This proposed section was not included in the November 1990 information document. It incorporates the requirements of ISO 9001 4.5 "Document control."

Under proposed § 820.40, all manufacturers must establish document controls to ensure the clear and precise control of all documents that are required by the CGMP regulations. These controls include establishing a formal, documented system that defines how and by whom documents will be produced, reviewed, and approved, and the process to be used for updating documents and defining the responsibility for the distribution and maintenance of all required documents and the removal of obsolete documents.

Proposed § 820.40(a) was not included in the November 1990 information document. This section of the proposed CGMP regulation incorporates the requirements of ISO 9001 4.5.1 "Document approval and issue." It requires manufacturers to designate employees to review and approve all documents prior to distributing them. The 1990 information document suggested modifying current requirements in § 820.100 to better control document issuance and obsolete documents. These controls are set out in proposed § 820.40(b).

24. In response to the November 1990 information document, several comments said that all obsolete documents should not have to be removed, because they may still have use. The agency disagrees. If obsolete documents still have use, they are not obsolete, but may require reidentification.

25. Other comments said that use of the term "practical number" needs interpretation.

After reviewing these comments, FDA believes it is best to delete the term, and will address the issue in future guidelines.

Proposed § 820.40(c), which requires certain controls for specification changes, was not included in the November 1990 information document in its present form. Reference in proposed § 820.40(c) to adequate validation of specification changes was mentioned in the November 1990 information document in addressing the need to qualify and validate specification changes. This section of the proposed CGMP regulation incorporates ISO 9001 4.5.2 "Document changes/modification."

Proposed § 820.40(c) is a clarification of § 820.100(a)(2) and (b)(3). Existing CGMP requirements state that the device design (including components, packaging, and labeling) and all production and quality system specifications and methods must be documented (§ 820.181). All changes to these specifications must also be documented (§ 820.100(a)(2) and (b)(3)). FDA's review of recall data indicates that many recalls occur because of failure to validate specification changes to ensure such changes are adequate for their intended use (Ref. 3). Proposed § 820.40(c) requires manufacturers to validate that changes are adequate for their intended use before implementation.

In addition, to ensure that each manufacturer fulfills its responsibility under 21 CFR 807.81 or 21 CFR 814.39, proposed § 820.40(c) contains a requirement to consider the need to submit a 510(k) or PMA supplement when significant changes are made to device or manufacturing process specifications.

26. Several comments said that requiring all specification changes to be validated, as was proposed in the November 1990 information document, is overly burdensome and unnecessary. The comments added that not all specification changes affect product function.

In response to the comments, the requirement in this proposed section to validate changes is modified to require that all changes that may affect quality must be validated. Quality is defined in proposed § 820.3(r).

E. Purchasing (Subpart E)

FDA is proposing to replace the requirements of § 820.80 with the proposed Subpart E—Purchasing Controls and Subpart H—Inspection and Testing. A similar proposal was included in the November 1990 information document. Subpart E incorporates the requirements of ISO 9001 4.6 "Purchasing."

The failure to implement adequate component controls has resulted in a significant number of recalls due to component failures. Most of these were due to unacceptable components provided by suppliers (Ref. 3). FDA believes that the explicit addition to CGMP requirements of the purchasing controls of ISO 9001 will provide additional assurances that only acceptable components are used.

To ensure that purchased items and services conform to specifications, purchasing must be carried out under adequate controls, including the assessment and selection of suppliers, the clear and unambiguous specification of requirements and the performance of suitable inspection and testing. Each manufacturer must establish an appropriate mix of supplier and incoming controls to ensure that purchased components, finished devices, and manufacturing materials are acceptable for their intended use.

The specifications for the finished device cannot be met unless the individual parts of the finished device meet specifications. The most efficient and least costly approach to ensure that only acceptable components, packaging, and labeling are used is to ensure that only acceptable components, packaging, and labeling are received. This means that only suppliers who can consistently meet specifications should be used. Thus, proposed § 820.50(a), which incorporates ISO 9001 4.6.2 "Assessment of sub-contractors," requires manufacturers to assess the ability of suppliers to provide acceptable components, finished devices, manufacturing materials, and services.

The extent of the assessment, and the type and extent of control exercised by the manufacturer, are dependent upon the significance of the product or service purchased, and, where applicable, upon the previously demonstrated capability and documented performance of the

supplier. Selected suppliers should have a demonstrated capability to provide components, finished devices, manufacturing materials, or services that meet all of the needed requirements. Where it is not practical to assess the capability of suppliers and contractors, manufacturers must ensure the adequacy of supplied and contracted components, finished devices, manufacturing materials, and services through traditional incoming inspection or testing, with the degree of inspection and testing based on the intended use of the product or service.

27. Several comments stated that the assessment of supplier/subcontractor requirements, as set forth in the November 1990 information document, were too detailed. Other comments pointed out that each manufacturer does establish its own detailed criteria for supplier selection and should be left to do so on its own. FDA has reviewed the comments and has reduced the detail contained in the November 1990 information document.

Another comment suggested that quality is not the only consideration when selecting a supplier. Although FDA agrees that quality is not the only consideration when selecting suppliers, it is nevertheless a crucial consideration and may not be disregarded.

Proposed § 820.50(b) incorporates the requirements of ISO 9001 4.6.3 "Purchasing data" and specifies that controls must be established to ensure that specifications are properly described in the purchasing documentation. Often, purchased components do not meet the required specifications because the specifications provided to the supplier are unclear or incomplete. Ensuring that purchased components, finished devices, packaging, labeling, manufacturing materials, and services meet specifications begins with a clear definition of requirements. The proposed regulation specifies that controls must be established to ensure that specifications are properly described in the purchase or contract documentation.

28. Several comments, in response to the November 1990 information document, referred to the need for flexibility in requiring that purchasing documents contain "data clearly describing the item or service ordered."

In response to the comments, FDA has revised this proposed requirement. The proposed requirement now specifies that the purchasing documents shall describe or, when appropriate, reference published standards or specifications for the item or service purchased.

29. Several comments expressed concern that mandating that a designated individual review and approve purchasing documents was overly restrictive and did not allow for computerized checking.

In response to the comments, the requirement has been revised and no longer includes a reference to a designated individual. Nevertheless, because accountability is crucial, the signature of the person responsible for approving a purchasing document must be recorded.

F. Identification and Traceability (Subpart F)

i. Identification and traceability

Proposed § 820.60 imposes general controls to ensure that components, finished devices, and manufacturing materials are properly identified until they leave the manufacturer's control, but does not mandate traceability for noncritical devices. However, when a noncritical device manufacturer decides to establish traceability, traceability must be established using current, acceptable practices, i.e., identification such as serial or control numbers must be assigned.

The requirements in proposed § 820.60 were included in the November 1990 information document and incorporate the general requirements of ISO 9001 4.8 "Product identification and traceability."

30. Several comments, in response to the November 1990 information document, said that traceability should be limited to critical devices. While FDA was not suggesting that traceability was required for noncritical devices, the point has been clarified by placing traceability requirements for critical devices under a separate section in proposed § 820.65.

ii. Critical devices, traceability

Proposed § 820.65 retains traceability requirements for critical devices and is a supplement to ISO 9001.

31. Several comments agreed that the elimination of "critical component" was overdue, but claimed that not every component requires traceability even in a critical device.

FDA does not agree with these comments. Where traceability of components is important to prevent the distribution of nonconforming critical devices, critical device manufacturers must maintain traceability of components to a level that will enable the identification of the quality status of specific lots and batches of components, so that a problem component, or potential problem components, can be identified and traced to the supplier.

While FDA understands that traceability entails additional cost, it reminds manufacturers that, if a product recall is necessary, more devices would be subject to recall if lots of specific devices are not traceable, with associated higher recall costs to the manufacturer.

G. Production and Process Controls (Subpart G)

i. Process control

Subpart G—Production and Process Controls identifies the production conditions and controls that must be addressed when manufacturing medical devices. All are existing CGMP requirements, interpretation of CGMP's, or revisions of existing CGMP requirements, some of which are relocated from other parts of the CGMP regulation.

Proposed § 820.70(a) will require manufacturers to establish and implement sufficient and adequate process controls to ensure that the finished devices meet specifications. This is currently a requirement in § 820.100. No changes were suggested in the November 1990 information document for this proposed section; therefore, no comments were received. This section incorporates ISO 9001 4.9.1 "General." Written production methods, procedures, and workmanship criteria are required where deviations from device specifications could occur as a result of the absence of these production process controls. The proposed requirements are a clarification of the existing requirements in § 820.100(b).

Proposed § 820.70(b) duplicates existing § 820.46, except that static electricity is added to the list of conditions which may require control. Existing § 820.46 is redesignated as proposed § 820.70(b) because these requirements are pertinent to the production process. Because these proposed requirements are existing CGMP requirements, they were not included in the November 1990 information document and no comments were received. The requirements of this section of the proposed CGMP regulation are not contained in ISO 9001 and are a supplement to ISO 9001 4.9 "Process control."

Proposed § 820.70(c) is a combination of existing §§ 820.25(b) and 820.56. These requirements are redesignated as § 820.70(c) because they are pertinent to the production process. This proposed section was not included in the November 1990 information document and, therefore, no comments were received. Proposed § 820.70 (d), (e), and

(f) are existing CGMP requirements. The requirements of this section of the proposed CGMP regulation are not contained in ISO 9001 and are a supplement to ISO 9001 4.9 "Process control."

The proposed requirements in § 820.70(g) duplicate existing requirements in existing § 820.60, with some minor additions. For example, the phrase "adequate for its intended use" and the word "use," which are not contained in the language of existing § 820.60, are used in proposed § 820.70(g) to clarify that manufacturing equipment must be "adequate for its intended use," and to clarify that the equipment must be appropriately designed to facilitate not only maintenance, adjustment, and cleaning, but also use.

The proposed requirement in § 820.70(g), that manufacturing equipment must be adequate for its intended use, was included in the November 1990 information document. There were no comments on the suggested revision. The other proposed changes were not included in the information document. The requirements of this section of the proposed CGMP regulation are not contained in ISO 9001 and are a supplement to ISO 9001 4.9 "Process control."

Proposed § 820.70(h) is a combination of the CGMP requirements for automated operations contained in existing §§ 820.61 and 820.195. Such operations must be evaluated, and when necessary, the software validated according to formal protocols. The language of this section was included in the November 1990 information document. It was also cited as substitute language for existing requirements in that document which proposed deleting existing requirements to validate automated systems in § 820.61 and § 820.195. The requirements of this section are a supplement to ISO 9001.

32. Comments which addressed proposed requirements to validate automated systems stated that not all software requires validation; for some software, inspection and testing are alternatives.

FDA disagrees. Inspection and testing are not alternatives to validation; they are means to accomplish validation. Thus, inspection and testing may, in some cases, be appropriate to ensure that software is acceptable for its intended use in a production process. Such inspection and testing should be documented in a written protocol; this may accomplish validation. However, all software used in production must be reviewed for adequacy and properly validated before use.

ii. Special processes

FDA added proposed § 820.75 which provides requirements for special processes to clarify that process validation is required for many processes and is a CGMP requirement. A "Special process" is defined in proposed § 820.3(aa). Because the results of special processes cannot be verified by inspecting or testing the process results, special processes must be validated and carefully monitored during processing to ensure they will consistently produce the desired results.

Although proposed § 820.75 was not included in the November 1990 information document, process validation was discussed as a CGMP requirement in that document. The November 1990 information document did not use the term "special processes," as is done in proposed § 820.75, but otherwise described such a process. Many manufacturers have expressed confusion as to which processes should be validated in a given manufacturing process. FDA believes the clarification of validation requirements in proposed § 820.75, in conjunction with the definition of "Special process" in proposed § 820.3(aa), will assist manufacturers in deciding which processes to validate. This section incorporates the requirements of ISO 9001 4.9.2 "Special processes."

H. Inspection and Testing (Subpart H)

i. Inspection and testing

The requirements proposed in § 820.80 were not included in their present form in the November 1990 information document because they are primarily existing CGMP requirements. These requirements incorporate the provisions of ISO 9001 4.10 "Inspection and testing" and are incorporated in existing §§ 820.20(a)(4) and 820.80.

Proposed § 820.80(a) will require manufacturers to formalize assessment methods and procedures and ensure that they are adequate for their intended use and performed correctly. During production there are typically three phases where inspection, testing, or verification should take place: When receiving raw materials or components; during the manufacturing process; and prior to release of the finished devices. It is important that each of these activities be controlled and the results recorded in quantitative data to provide objective evidence of the completion of the operation. Manufacturers must use a combination of in-house inspection and testing methods, validation, and process control, to ensure conformance to design and process specifications. Proposed § 820.80(b) contains basically the same requirements as existing § 820.80(a). This section of the proposed CGMP regulation incorporates ISO 9001 4.10.1 "Receiving inspection and testing."

Each manufacturer must establish an appropriate mix of supplier and incoming controls to ensure that purchased components, finished devices, packaging, labeling, and manufacturing materials are acceptable for their intended use. The proposed language for this requirement will provide manufacturers some flexibility in deciding whether to carry out acceptance procedures at the supplier, under contract, or in-house, or some combination of these approaches.

The requirements in proposed § 820.80(c) are now contained in existing §§ 820.20(a)(2) and, 820.100 and therefore were not proposed in the information document. They incorporate the provisions of ISO 9001 4.10.2 "In-process inspection and testing." Proposed § 820.80(c) requires manufacturers to conduct in-process inspections and tests according to written procedures and to record the results, when the manufacturing process could affect the product's quality. The results must be recorded and maintained in the device history record.

Proposed § 820.80(d) is essentially identical to § 820.160, except that the requirement for actual or simulated use testing is being moved to proposed § 820.30(g), and the requirement that addresses sampling plans is moved to proposed § 820.250. These requirements were not included in the November 1990 information document. FDA believes the requirement for simulated use testing set out in proposed § 820.30(g) will be more effective at the end of the design process and following changes to the device and process. A new requirement is added to ensure that all acceptance data are present and reviewed before finished devices are released for distribution. This is a clarification of the requirement in § 820.20(a)(1). Final inspections and tests alone are not sufficient to ensure that devices are manufactured according to the requirements of the device master record. Objective evidence must be provided and reviewed before devices are distributed.

FDA proposes to remove existing § 820.161 because these requirements are now incorporated under proposed §§ 820.90, 820.100, and 820.80(d).

A proposal that existing § 820.161 be relocated was included in the November

1990 information document. No comments specific to that proposal were received, other than the general comments on elimination of the critical device requirements. (See section III.A. of this document.) The requirements of proposed § 820.80(d) incorporate ISO 9001 4.10.3 "Final inspection and testing."

Proposed § 820.80(e) clarifies that all inspection and test results must be recorded in the device history record and incorporates ISO 9001 4.10.4 "Inspection test records." This proposal was not included in the information document. It is consistent with existing § 820.184.

ii. Inspection and test equipment

Proposed § 820.84 consists of existing § 820.61, except that proposed § 820.84 (d) and (e) are added to ensure that, once calibrated, the integrity of the equipment calibration is maintained. This section incorporates ISO 9001 4.11 "Inspection, measuring, and test equipment."

The current requirement contained in § 820.61 to validate all automated production and quality assurance systems is being redesignated as proposed § 820.70(h), which contains a general validation requirement for all automated processes. Reference to removing and redesignating validation requirements for automated systems was made in the November 1990 information document. Comments on this point are addressed in section IV.G. of this document which discusses proposed § 820.70(h).

iii. Inspection and test status

Proposed § 820.86 incorporates ISO 9001 4.12 "Inspection and test status" and requires manufacturers to identify the inspection and test status of all components, finished devices, and manufacturing materials at all phases of purchasing and production. This proposed section was not included in the November 1990 information document. It must be possible to quickly and clearly establish the inspection status at any phase of purchasing and production and, in particular, identify those items which do not conform to specifications. This requirement is already a CGMP requirement contained in existing §§ 820.80 and 820.100.

I. Nonconforming Components and Devices (Subpart I)

Proposed § 820.90 is a revision of existing §§ 820.115 and 820.116 and sets forth the requirements for nonconforming components and devices. Similar proposed requirements were included in the November 1990 information document. Proposed § 820.90 incorporates the requirements of ISO 9001 4.13 "Control of nonconforming product."

Each manufacturer's quality system must include controls that will ensure that components, finished devices, or manufacturing materials that do not conform to specifications are not inadvertently used or distributed. This section is applicable to manufactured as well as purchased components, finished devices, or manufacturing materials and returned finished devices.

Purchasing and manufacturing processes sometimes yield suspect or defective items. In order to ensure that only acceptable finished devices are distributed, manufacturers need methods for preventing further processing, distribution, or installation of nonconforming components, finished devices, and manufacturing materials. The method of identifying and determining the disposition of nonconforming components, finished devices, and manufacturing materials will vary, depending upon the type of device produced. In all cases, the methods and procedures used to identify and control nonconformance must be documented and included in the device master record. The investigation of nonconforming items is an important part of the quality system. The results of the investigation of nonconformance provide valuable information that may be used to prevent reoccurrence of nonconforming components and devices. This activity, if properly designed, can also result in cost savings to the manufacturer and increased customer satisfaction.

33. With respect to the investigation of nonconforming components and finished devices, several comments stated that an investigation is not always necessary when a nonconforming product is identified.

FDA disagrees. Unless the defect is solely cosmetic (e.g., paint or polishing defects), manufacturers must investigate and establish both the cause and effect of the defect or nonconformance. If the cause and effect of nonconformance is already suspected, then the documented investigation need only confirm the cause and effect. When cause and effect are unknown, documented investigation must be conducted to the level necessary to determine the cause of nonconformance and the effect on quality.

34. One comment said that there are numerous types of repair and rework activities that take seconds to perform but would take hours to write up.

FDA believes the proposed good manufacturing practices accommodate this comment. The recordkeeping requirement is intended to ensure that nonconforming components and finished devices are identified and not distributed until they meet specifications. Each manufacturer must develop recordkeeping sufficient to achieve this requirement that is appropriate to the activity.

35. One comment asked if this section applied to the release of nonconforming materials without repair, rework, or reprocessing. When this disposition is chosen, the manufacturer must evaluate and document the decision and ensure that it does not compromise the finished device safety and effectiveness.

J. Corrective Action (Subpart J)

The regulations set forth in this proposed subpart incorporate the specifications contained in ISO 9001 4.14 "Correction Action," which are implicit in existing § 820.20(a)(3) and (a)(4). The ISO requirements are modified in proposed subpart J to clarify that corrective action activities must be documented and to create order in the approach to problem detection and resolution. Because proposed § 820.100 incorporates the current requirements under § 820.162, existing § 820.162 is being removed from the revised CGMP regulations.

Proposed § 820.100 requires manufacturers to establish a program for the collection, correlation, and evaluation of internal and external quality data for the purpose of detecting and preventing quality problems. A manufacturer is also required to develop solutions to any problems found, to identify, implement, verify, and document corrective action. These proposed requirements were included in the November 1990 information document under the organization section. Trend analysis was suggested in the information document as a means of evaluating data.

Proposed § 820.100(a)(1) through (a)(5) require that each manufacturer's quality system must include a documented, systematic method for identifying and eliminating the causes of nonconforming components, finished devices, and manufacturing materials. Under proposed § 820.100(a)(6), relevant quality information must be regularly reported to and monitored by management. Management must compare the information with quality objectives and identify opportunities for improvement in design, manufacturing, and the quality system.

36. Several comments objected to the specification of just one method (trend analysis) as a quality assurance tool. In proposed § 820.100(a)(1), the

requirement to evaluate data for nonconforming products is rewritten to align with ISO 9001 and to specify that trend analysis is to be conducted. The proposed requirement specifies that manufacturers must analyze all quality data, including complaint files and service reports, to detect systematic problems that cause nonconformance and other quality problems. Trend analysis is not a single analytical method. Rather, trend analysis requires a manufacturer to use an appropriate statistical methodology to determine whether systemic or unanticipated problems are occurring with a product or whether problems are occurring at a greater than anticipated frequency. Trend analysis is the appropriate method for conducting this analysis.

K. Handling, Storage, Distribution, and Installation (Subpart K)

i. Handling

The requirements of proposed § 820.120 are a revision of existing § 820.40. This proposed section incorporates ISO 9001 4.15.2 "Handling," and was not included in the November 1990 information document.

Each manufacturer must establish, as part of the quality system, documented controls that will ensure that the activities involved in the handling, moving, and holding of components, finished devices, and manufacturing materials will have no adverse effects on these items. Controls shall include provisions for preventing mixups.

ii. Storage

Proposed § 820.122 is a combination and revision of the current storage requirements in §§ 820.80(b), 820.40, and 820.150. This section incorporates ISO 9001 4.15.3 "Storage" and was not included in the November 1990 information document. Proposed § 802.122 specifies that the quality system must include controls for all storage areas that are adequate to ensure that the quality of components, finished devices, and manufacturing materials are not adversely affected during devices storage and that all deteriorated or rejected and nonconforming items are identified to prevent inadvertent use.

iii. Distribution

Proposed § 820.124 is a combination of existing §§ 820.150 and 820.151. The present regulation requires only critical device manufacturers to maintain distribution records. Proposed § 820.124 requires all manufacturers to maintain distribution records. This section incorporates ISO 9001 4.15.5 "Delivery." Proposed § 820.124 is a revision of the suggested language in the November 1990 information document and, therefore, some of the comments no longer apply.

37. Most comments on the November 1990 information document that are pertinent to the revised language in proposed § 820.124 were concerned with the imposition of the critical device requirement to maintain distribution records upon all medical devices. One comment suggested clarifying that control numbers are required for critical devices only.

FDA believes it is crucial for the agency to have access to distribution records in order to ensure that manufacturers are properly complying with recall and complaint investigation requirements, and to ensure that all defective devices are withdrawn from points of use.

iv. Installation

Proposed § 820.126 is identical to § 820.152, except that a requirement is added for a record to be maintained of the installation check. Instructions and procedures for installation must include criteria for determining if the installed device(s) is operating properly. A record of the installation check is necessary to provide evidence that the check was made. This proposed revision of § 820.152 was not included in the November 1990 information document and is a supplement to ISO 9001.

L. Packaging and Labeling Control (Subpart L)

Proposed subpart L consists of a revision of existing §§ 820.120 and 820.121 and a duplication of existing § 820.130.

i. Device packaging

Proposed § 820.160 is identical to existing § 820.130. Thus, this section was not included in the November 1990 information document. This section incorporates ISO 9001 4.15.4 "Packaging."

ii. Device labeling

Proposed § 820.162 is a revision of existing § 820.120 and includes the proofreading requirements of existing § 820.121(b). The revision states that, when labels and other labeling are proofread, a record must be made of the activity. A record is necessary to provide evidence that the labeling was proofread. The modification of existing § 820.120 was included in the November 1990 information document and is a supplement to ISO 9001.

38. One comment said that the requirement to allow proofreading should be expanded to allow proofreading of the labeling artwork or specifications, instead of samples. FDA believes it is crucial that the actual labeling is reviewed prior to use to ensure that it is accurate. A significant number of recalls occur each year due to inaccurate labeling (Ref. 4).

iii. Critical devices, labeling

Proposed § 820.165 is identical to existing § 820.121(a). The remaining labeling requirements for critical devices in existing § 820.121(b) and (c) are covered by other proposed sections. As mentioned previously, existing § 820.121(b) is being included in proposed § 820.162. Existing § 820.121(c) is covered by the general requirement of proposed § 820.120 that requires labeling to be stored to prevent "damage, deterioration, or other adverse effects" such as mixups. Proposed § 820.165 was not included in the November 1990 information document and is a supplement to ISO 9001.

39. Several comments said that it should be clarified that traceability or control numbers are required for critical devices only. In response to these comments, a separate section is provided for critical device requirements.

M. Records (Subpart M)

The proposed requirements under subpart M consist of revisions of the existing subpart J of the CGMP regulation.

i. General requirements

A requirement for legibility, traceability, and storage of records, which is not presently contained in existing § 820.180, is added to proposed § 820.180. All records maintained to meet the requirements of the CGMP regulation must be legible and clearly identified as to the entity to which they refer and must be stored in a manner to prevent deterioration, damage, or loss. When required under the regulation, the records maintained must include pertinent subcontractor quality records. Backups are required when records are stored on a computer. The remainder of the requirements in this section are requirements of existing § 820.180. No changes for this section were suggested in the November 1990 information document. This section incorporates the applicable requirements of ISO 9001 4.16 "Quality records." The confidentiality and record retention period requirements remain the same as in the existing CGMP regulation.

ii. Device master record

Proposed § 820.181 is revised to reflect new documentation requirements and use of the term "Quality system." Proposed § 820.181 is a supplement to ISO 9001. Any changes made to the device master record (DMR) must now be controlled as required by proposed § 820.40. Documentation of software design specifications and software source code is added in proposed § 820.181(a). In proposed § 820.181(c), "quality system procedures" replaces the former "quality assurance procedures" and "verification checks and verification apparatus used" replaces the former quality assurance terminology. Validation protocols and validation results must also be included in the DMR as set forth in revised § 820.181(c).

Documentation of installation, maintenance and servicing procedures in the DMR is required under proposed § 820.181(e).

Existing § 820.182 is being removed. These requirements are now being covered by proposed §§ 820.50 and 820.184. The deletion of existing § 820.182 was suggested in the November 1990 information document. No comments were received.

iii. Device history record

The existing requirements of § 820.184 are being revised to include a requirement that the actual labeling used must be included or its location referenced in the device history record.

Suggested language for the revised device history record requirements was included in the November 1990 information document. The language in proposed § 820.184 is a revision of the suggested language in the information document.

40. Comments in response to the November 1990 information document said that the requirement for specific labeling is not necessary if the manufacturer complies with the device master record requirements. FDA disagrees. Many recalls have occurred each year due to incorrect labeling (Ref. 4). Including the specific labeling in the device history record and requiring review of the record will help to ensure that proper labeling is used. The requirements of proposed § 820.184 are a supplement to ISO 9001, although records applicable to the device history record are required throughout ISO 9001.

iv. Complaint files

Proposed § 820.198 sets out the requirements for complaint files. Written procedures must be provided that describe the complaint handling process, that specify the activities to be conducted, and that address all required functions, including: Responsibilities, recordkeeping, complaint investigation, and the identification of events which must be reported under the MDR regulations at part 803. Proposed § 820.198 also clarifies that the requirements of § 820.198 apply not only to the device, but also to the packaging and labeling of a device. In addition to the current CGMP requirement to investigate complaints, proposed § 820.198(b) clarifies that complaint investigations must include a determination of whether there was an actual device failure, a determination of whether the device was involved in an injury or death, and a determination of the relationship of the device to the incident. These proposed clarifications were included in the November 1990 information document. Proposed § 820.198 is a supplement to ISO 9001.

Any complaint that is also reportable under part 803 must meet all the requirements of § 803.26. Firms that receive complaints or reports from user facilities, distributors, or other sources, that do not contain all the data or information required under part 803 or proposed § 820.198 must contact the reporter and either obtain the missing data or document why the missing information cannot be obtained. Followup should include:

(1) Collection, analysis, and testing of defective devices or samples, whenever possible.

(2) Failure analysis or other evaluation necessary to determine assignable cause.

(3) Review of the product's complaint history for the same or similar problems, including any recent changes in design, instructions, or production techniques.

(4) Formulation of approaches to correct any problems found.

Proposed § 820.198 also clarifies that complaints subject to the provisions of the section may be from any source. While copies of complaints may be contained in other files, such as litigation files, to facilitate processing, the original information regarding the complaint must be maintained in the complaint file specified in proposed § 820.198.

The language in proposed § 820.198 also clarifies that the record of investigation must contain the results of the investigation, including the corrective action taken, and must document the reason for a lack of a reply to the complainant. This information is necessary in order to show that a proper investigation was conducted. In addition to the name of the complainant, the complainant's address and phone number must be included in the record of investigation. This information is necessary to facilitate followup of complaints.

When the complaint involves a manufacturing site, a copy of the complaint and the record of the investigation must be transmitted to the manufacturing site. This is necessary to ensure that the actual manufacturer has all of the information relating to the complaint.

41. Several comments in response to the November 1990 information document said that it is not always possible to determine if there was a device failure. If, after adequate investigation, it is not possible to determine if a complaint involved a device failure, FDA believes that the actions taken by the firm and the results should be recorded in the record of investigation.

42. Several comments said that, as worded, the language that requires the corrective action to be recorded implies that every complaint will result in corrective action.

FDA does not believe the language in proposed § 820.198 makes this implication. Each manufacturer should develop a record for recording complaint investigations that includes provisions for recording corrective actions. When no corrective action is taken, the reason must be recorded. Those events that do not require corrective action may be identified in the written complaint processing procedures.

43. Several comments addressed trend analysis. One comment said that trend analysis was good business sense. One comment said that trend analysis should be added to the audit requirements; another said that trend analysis may not always be appropriate and that concern should be oriented toward significant problems, not just recurring problems of no practical significance.

FDA agrees that trend analysis makes good business sense, but has deleted reference to it in proposed § 820.198. However, proposed § 820.100 does require manufacturers to conduct trend analysis of complaints and other sources of quality data to detect systematic quality problems. FDA notes that trend analysis is the accepted method for detecting systemic problems, while the purpose of the quality audit is to periodically evaluate the applicability and effectiveness of the quality system. The evaluation of trend analysis procedures may be part of the overall audit evaluation. Trend analysis of quality data must be a routine function

of the quality system and is subject to FDA review.

44. With respect to maintaining copies of complaints at the manufacturing site, when the formally designated unit for processing complaints is located at a site separate from the actual manufacturing establishment several comments said that only those records of reviews, findings, and corrective actions that result in modifications to manufacturing operations should be maintained at the manufacturing site.

In response to these comments, FDA is revising the language relating to this proposed requirement to state that copies of complaints should be transmitted to and maintained at the manufacturing site when the complaint involves the manufacturing site.

N. Servicing and Returned Devices (Subpart N)

Proposed § 820.200 will require manufacturers who service devices or who authorize agents to service devices to maintain service records and written procedures for implementing the service activity. Service record data must be reviewed for systemic problems, and systemic problems acted upon when detected.

The quality system established by manufacturers who service devices for users must extend to the servicing operation. Information contained in service records is an important source of device experience information that may be used to detect systematic quality problems. Thus, an important part of the program must be the maintenance of servicing records, the periodic review and evaluation of these records, and the feedback of device problems into the quality data analysis program required under proposed § 820.100. Requirements of the quality system which are applicable to servicing include training, quality audit, component and documentation controls, inspection and testing, nonconforming component and device controls, measuring and test equipment controls, purchasing, and records. Controls must be in place that will ensure that serviced devices meet specifications and must include written procedures for managing the servicing activity.

Suggested language for servicing requirements was included in the November 1990 information document. That language was revised to arrive at the language being proposed for § 820.200. This section incorporates ISO 9001 4.19 "Servicing."

45. Several comments to the November 1990 information document wanted to know if the servicing requirements applied to service and repair at a customer's place of business.

FDA considers the proposed servicing requirements to apply to any servicing conducted or controlled by a finished device manufacturer.

46. Several comments said the language that was suggested to revise the CGMP regulation was too detailed and recommended that the ISO 9001 language be used in lieu of the suggested language. FDA agrees with these comments. The language in proposed § 820.200 is revised to eliminate much of the detailed language contained in the November 1990 information document.

As now written, the requirements in proposed § 820.200 specify that each manufacturer must conduct an analysis of service reports to detect systematic quality problems. When a systemic problem is detected, or a problem is detected that involves a death, serious injury, safety hazard, or recurring failure, that problem should be treated as a complaint and processed according to the requirements in proposed § 820.198. When such problems are identified, a determination must be made as to whether the event is reportable under part 803. Therefore, instructions for reporting under the MDR regulation must be provided in the procedures established to manage the servicing activities.

O. Statistical Techniques (Subpart O)

Proposed § 820.250 incorporates ISO 9001 4.20 "Statistical Techniques" and states that, when appropriate, statistical techniques must be applied to ensure the acceptability of process capability and device characteristics. The use of statistical methods can be beneficial in most aspects of data collection, analysis, and application. They may be used in determining process control, forecasting, verification and measurement, or assessment of quality.

When manufacturers develop sampling plans, the plans must be proven to be statistically sound for their intended use. In addition, sampling plans must be periodically reviewed for adequacy, especially when the plans fail to detect nonconformance. Sampling based upon a statistical rationale is now required by §§ 820.81 and 820.160.

The requirements of proposed § 820.250 were not included in their present form in the November 1990 information document. However, reference to the requisite statistical basis for sampling plans was made in that document with respect to the acceptance of components.

V. Statutory Authority and Enforcement

FDA's statutory authority to issue CGMP regulations is derived from sections 501, 502, 515, 518, 519, 520, 701, 704, and 801 of the act (21 U.S.C. 351, 352, 360e, 360h, 360i, 360j, 371, 374, and 381).

Section 701(a) of the act authorizes FDA to promulgate substantive, binding regulations for the efficient enforcement of the act. *Weinberger* v. *Hynson, Westcott & Dunning, Inc.*, 412 U.S. 609 (1973); see also *Weinberger* v. *Bentex Pharmaceuticals, Inc.*, 412 U.S. 645, 653 (1973); *National Assn. of Pharmaceutical Manufacturers* v. *FDA*, 637 F.2d 877 (2d Cir. 1981); *National Confectioners Assn.* v. *Califano*, 569 F.2d 690 (D.C. Cir. 1978); *National Nutritional Foods Assn.* v. *Weinberger*, 512 F.2d 688 (2d Cir.), cert. denied, 423 U.S. 827 (1975). Section 520(f)(1)(A) of the act, as amended by section 18(d) of the SMDA, specifically authorizes the agency to promulgate regulations that prescribe, and require conformance to, CGMP for the manufacture, preproduction design validation, packing, storage, and installation of device. Section 519(a) of the act (21 U.S.C. 360i(a)) also authorizes the agency to issue regulations requiring the manufacturers of devices to maintain and provide records to ensure that devices are not adulterated, misbranded, unsafe, or ineffective. FDA's CGMP regulations for medical devices are substantive regulations with the force and effect of law. *United States* v. *Undetermined Quantities of Various Articles of Device * * * Proplast II*, 800 F. Supp. 499, 502 (S.D. Tex. 1992); *United States* v. *789 Cases * * * Latex Surgeons' Gloves*, 799 F. Supp. 1275, 1287 (D.P.R. 1992).

CGMP regulations for medical devices are enforced through sections 301, 302, 303, 304, 501, 502, and 801 of the act (21 U.S.C. 331, 332, 333, 334, 351, 352, 381). Section 501(h) of the act deems a device to be adulterated if the methods, facilities, or controls for the manufacture, packing, storage, or installation of the device do not conform with good manufacturing practice requirements under section 520(f)(1) of the act (*Proplast II*, 800 F. Supp. at 503; *789 Cases*, 799 F. Supp. at 1285). Under section 502(t)(2) of the act, a device is deemed misbranded if there is a failure or refusal to furnish any material or information required by section 519 of the act respecting a device.

Section 301 of the act (21 U.S.C. 331) sets forth prohibited acts. Under section 301(a) of the act, the introduction of an adulterated or misbranded device into

interstate commerce is prohibited. Under section 301(b) of the act, the adulteration or misbranding of a device in interstate commerce is prohibited. Under section 301(k) of the act, any act which results in a device being adulterated or misbranded after its shipment in interstate commerce is prohibited. Section 301(q)(1)(B) of the act prohibits the failure or refusal to furnish any information required by section 519 of the act.

Persons who commit prohibited acts in violation of section 301 of the act may be enjoined under section 302(a) of the act and may be subject to criminal prosecution under section 303 of the act. Devices that are adulterated within the meaning of section 501(h) of the act, or misbranded within the meaning of section 502(t)(2) of the act, are subject to civil sanctions of seizure and condemnation under section 304(a)(2) of the act.

In addition to the criminal and civil enforcement actions mentioned above, section 17 of the SMDA added section 303(f) to the act. Section 303(f) of the act provides that manufacturers, importers, and distributors may be subject to civil penalties for those violations of sections 519(a) or 520(f) of the act that constitute a significant or knowing departure from these requirements or a risk to the public health. Civil penalties may not exceed $15,000 for a single violation, and may not exceed $1,000,000 for all such violations adjudicated in a single proceeding.

VI. Environmental Impact

The agency has determined under 21 CFR 25.24 (a)(8) and (e)(2) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

VII. Economic Impact

A. Summary

FDA has examined the costs and benefits of the proposed rule to revise the CGMP regulations covering medical devices (21 CFR part 820) in accordance with Executive Order 12866 and the Regulatory Flexibility Act (Pub. L. 96–354). The detailed data for this analysis were developed by ERG, under contract to FDA, and the full report, "Economic Analysis of Proposed Revisions to the Good Manufacturing Practices Regulation for Medical Devices," is on file at the Dockets Management Branch (address above).

The objective of the proposed rule is to reduce the number of fatalities and injuries attributable to defective medical devices. The U.S. Office of Management and Budget asks that Federal agencies justify new regulations by demonstrating that the problem that the regulation is designed to correct cannot be adequately addressed by other measures. For example, in some circumstances, private markets or industry guidelines can be relied on to abolish unwarranted risks. In this instance, FDA finds that private market incentives do not adequately reduce the risk of design-related device failures, because neither physicians nor consumers have all of the information needed to make adequate judgments of product quality and legal tort remedies, are slow, inefficient, and extremely costly.

The proposed CGMP regulations will extend the manufacturer's quality system in several areas, including design, purchasing, and servicing; and clarify or expand selected existing requirements. It will affect all medical device establishments engaged in the design, manufacture, contract sterilization, and packaging of medical devices. FDA considered two alternative levels of coverage for the preproduction design requirements of the proposal. The first alternative was to require compliance for all medical devices regardless of the potential public health risk. The second alternative was to exempt about 95 percent of the manufacturers of the lower risk, class I, devices from the preproduction design requirements. FDA found that the benefits from subjecting all device establishments, regardless of the class of device manufactured, to the preproduction design elements were not great enough to justify the cost. A summary of the detailed economic analysis of the proposed CGMP regulations is presented below.

Based on the ERG study, the total annual incremental costs to the U.S. industry of the proposed regulation are estimated to be about $84.5 million. These costs would be more than offset, however, by benefits to public health and by economic benefits to the medical device industry. FDA estimates that the benefits to public health would include over 50 fewer deaths and about 1,150 fewer serious injuries per year, which are now attributed to design-related device failures. Studies on the value of a statistical-life have reported estimates ranging from $1.6 million to $8.5 million.[1] Assuming an economic value of $5 million per fatality avoided, the monetary value of saving 50 lives each year would be $250 million. Therefore, the value of the public health benefits of preventing deaths alone easily exceeds the cost of compliance. Moreover, additional economic benefits to medical device establishments would result from cost savings due to fewer design-related product recalls, better product quality, and greater productivity. In addition, medical device establishments exporting to the EC would benefit from the harmonization of the CGMP regulation with the ISO 9001 quality standard. Because the EC is adopting ISO 9001 as a basis for its medical device manufacturing quality system, the harmonization of the two quality requirements will eliminate the need for device manufacturers to maintain different quality systems for each market.

FDA supports the ultimate goal of international harmonization of standards and regulations governing medical devices and the eventual mutual recognition of CGMP inspections between major device markets. While achievement of this goal is still in the future, the harmonization of quality standards is an important first step. The Health Industry Manufacturers Association has stated that reciprocity for quality assurance inspections could save the medical device industry millions of dollars as well as provide significant savings to governments.[2]

For individual establishments, the economic impact of the regulation will depend on a number of factors, such as the level of current compliance, the type of activities performed at the establishment, and the nature of the product. On average, the smaller establishments will bear a relatively greater economic burden.

B. Industry Profile

The U.S. medical device industry is among the most competitive sectors in the United States. It is characterized by a large number of innovative firms, many small, that produce an extremely diversified range of products. In 1991, the industry's domestic production was approximately $33.7 billion and accounted for 47.5 percent of total world medical device output.[3] From

[1] Fisher, A., L. Chestnut, and D. Violette, "The Value of Reducing Risks of Death: A Note on New Evidence," *Journal of Policy Analysis and Management*, 8:88–100, 1989.

[2] Gilmartin, R. V., "The Benefits of Cooperation for Industry and Regulators Alike: A Global Perspective," presented at the Third Annual Global Medical Device Conference, October 2, 1992.

[3] Health Industry Manufacturers Association, "The Global Medical Device Report: Markets for Health Care Technology Products," vol. II, Washington, DC, 1992.

1989 to 1992 the average annual growth in medical device shipments was 9.7 percent compared to an average of less than 1 percent for all U.S. manufacturing. The U.S. Department of Commerce projects continued growth in medical device shipments of 3 to 7 percent through 1997.[4]

Exports are an important factor in the competitiveness of the domestic industry. In 1991, exports were $7.9 billion and accounted for about 23 percent of medical device value of shipments, whereas imports were only $4.1 billion or about 12 percent of domestic consumption.[5] With growth in the domestic market for medical devices projected to slow with the advancement of cost containment measures, the export market would take on even greater importance.

Firms in the medical device industry are heterogeneous. They vary in size, product type, product and process technology, and rate of new product introductions. There are over 7,000 medical device establishments involved in the production of approximately 4,000 different types of devices. Sixty-two percent of these establishments are very small (fewer than 20 employees), while 27 percent are of medium-size (20 to 99 employees), 7 percent are large (100 to 249 employees), and 4 percent are very large (250 or more employees). (See Table 1). These size categories were developed to reflect relative size categories within the medical device industry and differ from the Small Business Administration definition of size. Under the Small Business Administration definition, almost all establishments would be small. FDA categorizes devices by class and criticality. Critical devices are defined as any device intended for surgical implant, to sustain life, or whose failure under normal conditions could result in serious injury or death. The distribution of affected establishments that manufacture or develop devices is presented by class and criticality in Table 2. Most of the establishments that manufacture, contract manufacture, or develop specifications produce class II devices (71 percent), while 8 percent produce class III and 21 percent produce class I devices. Only 10 percent of the establishments produce critical devices (a critical device can be class II or class III).

The class of devices manufactured, the extent of an establishment's current compliance with the proposed changes, the rate of new product introductions, and the size of the establishment are factors that affect the cost of compliance for individual establishments. In general, establishments producing class III and critical devices are subject to more stringent and costly premarket review and CGMP requirements but are also more likely to be in greater compliance with the proposed changes to the CGMP regulation. Also, larger establishments tend to have more formal procedures and more layers of management than smaller ones, increasing the cost and complexity of writing and implementing new procedures. However, because of their more formal structure, larger firms have already implemented many of the proposed changes to the CGMP regulations.

The rate of new product introductions has a major effect on the incremental costs of the proposed CGMP regulation. Based on a limited sample of 510(k) and PMA applications, ERG estimated that the average affected medical device establishment submits 1.1 new product applications per year (Table 3). The submittal rate by size of establishment varied from 0.6 applications per year from small and medium-sized establishments to 6.9 applications per year from very large establishments. Because a substantial number of establishments are small, they remain an important source of new product introductions.

The great diversity of this industry makes it extremely difficult to characterize. Medical devices are classified under one of six Standard Industrial Classification (SIC) codes—Surgical and Medical Instruments (3841); Surgical Appliances and Supplies (3842); Dental Equipment and Supplies (3843); X-ray Apparatus and Tubes (3844); Electromedical Equipment (3845); and Ophthalmic Goods (3851). However, many medical devices are produced by establishments whose primary classification is for another SIC, such as in vitro diagnostics (SIC 2835). An earlier FDA study[6] found primary classifications in over 150 different SIC codes for a significant number of manufacturing establishments registered with the agency.

C. Industry Costs

ERG estimated the total annual incremental cost of the proposed changes to the CGMP regulation at $84.5 million. This includes $6.3 million in one-time costs that were annualized over 5 years at a 10 percent discount rate. Table 4 lists the most costly of the new requirements.

Costs were based on the incremental tasks each manufacturer must perform to achieve compliance. To develop these estimates, ERG assembled a team of economists, industrial engineers, and other industry consultants, who addressed each compliance activity in turn, first assessing the state of current practice and next the level and cost of the needed additional tasks. These estimates take into account the added labor and capital resources that would be needed to move from existing compliance levels to new, more stringent levels required under the proposal. For the most part, ERG determined that most very large and large establishments are already in compliance with many of the new requirements and thus would not experience large increases in costs.

The great majority of the costs for all size establishments will be to establish preproduction design controls for new products. Therefore, the more innovative establishments will experience greater compliance costs than the less innovative establishments. The estimated annual preproduction design control costs total $62.1 million, which represents 74 percent of the total annual incremental cost of compliance. The most costly task within the preproduction design category is design verification ($49.2 million), which includes verifying design output. Other costly tasks are design review ($6.4 million), which encompasses conducting and documenting design review meetings; design changes ($4.0 million), which includes drawing, documenting, and maintaining design change procedures; and design and development planning ($2.5 million), which includes drafting and maintaining standardized plans for device design and development. The requirement for extending the quality system audit to new areas of production such as design and servicing ($5.2 million) and establishing greater purchasing controls ($7.9 million) are also relatively high cost items.

The projected average cost per establishment (Table 5) varies substantially across establishment size categories and by product type, design complexity, and innovation rate. For most sectors of the medical device industry (excluding dental and ophthalmics) the average annual incremental cost per establishment is estimated to be: $19,300 for small, $15,800 for medium, $27,800 for large,

[4] U.S. Department of Commerce, "U.S. Industrial Outlook," Washington, DC, 1993.

[5] Health Industry Manufacturers Association, "The Global Medical Device Report: Markets for Health Care Technology Products," vol. I, Washington, DC, 1992.

[6] Food and Drug Administration, "Baseline Data on Medical Device Industries in the Census of Manufacturers," (OPE Study 53), 1980.

and $11,600 for very large establishments. The dental and ophthalmic industries have a lower rate of new product development than other device industries and, therefore, a lower average cost of compliance ($8,800 per establishment versus $18,700).

Because average current compliance rates vary directly with establishment size and the majority of establishments are small, the largest share of the costs are incurred by small establishments, $50.2 million (59 percent), while the smallest share is incurred by very large establishments, $3.1 million (3.7 percent) (Table 6).

D. Benefits From Proposed Changes to the CGMP

The proposed changes to the CGMP regulation will provide public health benefits to medical device users and economic benefits to the medical device industry. Based on its review of medical device recalls over the past 4 years, FDA has estimated that 30 percent of all medical device product recalls are due to inadequate preproduction design controls. It is extremely difficult to judge how many of these recalls could have been avoided, ERG judged that a majority would have been prevented if manufacturers had fully implemented the proposed CGMP design controls.

1. Public Health Benefits

FDA requires manufacturers to submit an MDR when their device is associated with a patient or user death, serious injury, serious illness, or device malfunction. ERG used the MDR database to estimate the public health benefits of the proposed changes to the CGMP regulation. There were over 47,000 MDR's submitted to FDA in 1991. FDA reviews each report for cause and assigns it a code. An MDR is considered closed when the review is completed. At the time of this report, 22,674 of the 1991 MDR's were closed. Of these closed cases, FDA determined that 19 percent of the fatalities and 23 percent of the serious injuries were device-related. The bulk of the remaining incidents were due to user problems, but also include procedural problems and cases where cause could not be clearly established.

To estimate the total number of deaths and serious injuries for 1991 by cause, the MDR's that were still open were distributed across cause codes based on the 1988 through 1991 averages. To estimate the number of deaths and serious injuries due to design-related causes, ERG assumed that the percent of the device-related MDR's that were design-related MDR's was the same as that for recalls (30 percent). Because MDR's are substantially underreported[7], ERG made an upward adjustment in the number of MDR's of 20 percent for fatalities and 40 percent for serious injuries. Based on these assumptions, medical devices contributed to an estimated 72 fatalities and 1,576 serious injuries in 1991 due to design-related problems in class II and class III devices (Table 7).

To develop an approximate idea of the preventability of these incidents, ERG convened a panel of industrial engineers and regulatory specialists with extensive experience in the design of medical devices. Each panel member evaluated a random sample of 100 design-related recalls. ERG found that the expected value of their judgments implied that proper design controls would have prevented about 73 percent of these recalls. Based on this preventability ratio, ERG calculated that the proposal would prevent about 53 deaths and 1,150 serious injuries per year.

To verify the reasonableness of these estimates, FDA examined an alternative method of estimating the number of fatalities caused by design-related device failures. For this calculation, 3 years of design-related recalls were assumed to be linked to MDR fatalities that occurred for these devices 1 year before or 3 months after the date of the recall. This approach, which provides a lower-bound estimate, because not all relevant fatalities and subsequent MDR's would occur during this limited time period, found that about 60 deaths per year were due to design-related device failures. If 73 percent of such incidents could be avoided through compliance with the proposed CGMP regulation, 44 deaths per year would be prevented.

These estimates of the public health benefits from fewer design-related deaths and serious injuries represent FDA's best projections, given the limitations and uncertainties of the data and assumptions. It should be noted that the failure of just one widely used device can cause an exceptionally large number of deaths and injuries. For example over 500 fractures of the Bjork-Shiley convexo-concave heart valve, with over 300 deaths, have been reported since 1980. Worldwide, there are over 56,000 surviving recipients of this device and fractures still occur at a rate of 30 to 40 per year.

Moreover, the above numbers do not capture the quality of life losses to patients who experience less severe injuries than those reported in MDR's, who experience anxiety as a result of diagnosis or treatment with an unreliable medical device, or who experience inconvenience and additional medical costs because of device failure.

Medical device malfunctions are substantially more numerous than deaths or injuries from device failures and also represent a cost to society. Malfunctions represent a loss of product and an inconvenience to users and/or patients. Additionally, medical device malfunctions burden medical personnel with additional tasks, such as repeating treatments, replacing devices, returning and seeking reimbursement for failed devices, and providing reports on the circumstances of medical device failures. No attempt was made to quantify these additional costs.

2. Industry Benefits

The medical device industry would gain substantial economic benefits from the proposed changes to the CGMP regulations in three ways: cost savings from fewer recalls, productivity gains from improved designs, and efficiency gains for export-oriented manufacturers, who would now need to comply with only one set of quality standards.

An average of 359 medical device recall events per year were reported to FDA over the period 1988 to 1991. As stated above, FDA estimates that design-related deficiencies contributed to 30 percent of those recall events annually. Applying the 73 percent recall preventability factor, ERG projects that there would be 67 fewer recalls of class II and class III devices each year under the proposed CGMP regulation (Table 8). Although substantial medical device recall cost data were not available, ERG estimated that if the cost and distribution of medical device recalls were similar to those reported in previous drug and device recall studies, the industry would avoid roughly $45 million worth of recall expenses per year by adopting the new CGMP regulation.

ERG also found that the design control requirements in the proposed CGMP regulation would require manufacturers to integrate their design and production operations and that most industry experts believe that this change would lead to better quality products, more efficient engineering, lower manufacturing costs, and reduced product development time. These savings, however, could not be quantified.

Still another benefit of the revised regulation relates to the harmonization

[7] General Accounting Office, "Medical Devices: Early Warning is Hampered by Severe Underreporting," GAO/PMED-87-1, Washington, DC, 1986.

of the proposed CGMP rule with the ISO 9001 international standard. This change would especially benefit export-oriented establishments, because they would need to meet only one set of quality standards. The EC in particular is important because it is second only to the United States in market size and purchases $3.4 billion (43 percent) of U.S. medical device exports.[8] ERG could not derive quantitative measures of this benefit, however, due to the lack of data regarding implementation of the standard in the EC.

E. Costs and Benefits if all Device Classes Were Subject to Preproduction Design Requirements

If all device classes were subject to the proposed design control requirements the total annualized compliance cost would increase from $84.5 million to $91.3 million (Table 9), solely due to a $6.8 million increase in annualized compliance costs for class I devices. In contrast, ERG estimates that subjecting class I devices to the design control requirements would have no expected impact on the number of fatalities avoided. There would, however, be 108 fewer design-related serious injuries (Table 10) and 11 fewer design-related recalls (Table 11).

F. Economic and Small Business Impact

The ability of medical device establishments to pass on the added cost of the proposed changes will determine their economic impact on the industry. Under the current medical care system, the demand for medical devices tends to be price inelastic because they are often prescribed by physicians and frequently paid for by third parties. Thus, small price increases have not typically prompted significant declines in industry sales. Nonetheless, competitive pressures would rise under new health care cost-containment measures. Therefore, to examine the potential effect of the costs of compliance on the industry's competitive structure, ERG calculated the maximum impact on industry average prices and profits, using extreme scenarios.

Based on the assumption that all costs of compliance are passed through to the end user, with no loss in sales and no offset for avoided recalls or other industry productivity gains, ERG found that the average increase in the price of medical devices would be less than 0.2 percent. Estimated price increases ranged from 0.06 percent for X-ray Apparatus and Tubes (SIC 3844) and Electromedical Equipment (SIC 3845) to 0.24 percent for Dental Equipment and Supplies (SIC 3843) (Table 12). (The maximum price increase was calculated using aggregate compliance costs as a percentage of the value of shipments.) The price increases calculated by size of establishment suggest that small establishments will be under greater pressure to increase prices. The cost of compliance represented an average of 1.8 percent of the value of shipments for small establishments and only 0.01 percent for very large establishments.

To estimate the potential impact of compliance costs on medical device industry profits, ERG calculated after-tax compliance costs as a percentage of after-tax income for each medical device SIC (Table 12). Again, no adjustments were made for avoided recalls or expected productivity gains. If manufacturers have no ability to increase prices to offset the increase in compliance costs, this estimate represents an upper bound of the potential effect on entity income. Under these circumstances, the medical device sectors would incur reductions in net income ranging from about 1 percent (SIC 3844 and 3845, X-ray Apparatus and Tubes and Electromedical Equipment) to about 3 percent (SIC 3843 and 3851, Dental Equipment and Ophthalmic Goods). ERG concluded that such impacts may affect some establishments' decisions to develop new products where expected profits are marginal or highly uncertain, but judged that the level of incremental costs imposed by this regulation would not substantially lower the innovation rate of products with significant medical benefits.

In accordance with the Regulatory Flexibility Act, FDA has considered the effect of this action on small businesses and has determined that there will be a significant impact on a substantial number of small businesses. The increase in costs is greatest for small establishments due to the large number of small establishments in the industry (62 percent are small) and the lower rate of current compliance by small establishments. The actual added cost per establishment will vary by the establishment's current level of compliance, complexity of product design, product type, and rate of product innovation. Small establishments producing differentiated products or marketing to niche markets may not be at a disadvantage because of their ability to pass on the added cost of compliance. However, small establishments that compete with larger establishments based on price alone would suffer a drop in profits if they currently operate at a lower level of compliance than their competitors. For small start-up establishments that have not yet developed significant sales volume, regulatory costs would amount to a substantial fraction of company revenues.

FDA, through its Division of Small Manufacturers Assistance has a number of programs designed to assist small businesses. The Division of Small Manufacturers Assistance provides guidance materials, regional seminars and technical assistance that can help small businesses with their compliance activities. In addition, FDA's decision to exempt the majority of class I device manufacturers from preproduction design requirements decreases the cost of compliance by $6.8 million and minimized the potential burden on small establishments that manufacture class I devices. About 60 percent of that $6.8 million would have been borne by small establishments.

In summary, FDA concludes that the $84.5 million annual incremental cost to comply with the proposed changes to the CGMP regulation would be substantially offset by significant savings from avoided recalls and more importantly, the avoidance of deaths and serious injuries due to design-related device failures or malfunctions. FDA's estimate of public health benefits includes the prevention of about 53 deaths and 1,150 serious injuries annually. In addition, establishing preproduction design controls would result in better designed and higher quality devices and fewer device malfunctions or failures would reduce the inconvenience and expense of repetitive treatments or diagnoses. These public health benefits exceed industry's cost of compliance.

[8] Health Industry Manufacturers Association, "The Global Medical Device Report: Markets for Health Care Technology Products," vol. I, Washington, DC, 1992.

TABLE 1.—DISTRIBUTION OF AFFECTED ESTABLISHMENTS BY EMPLOYMENT SIZE

Type of establishment	Total [1]	Employment size [2]			
		Small (1–19)	Medium (20–99)	Large (100–249)	Very large (≥250)
Manufacturer	5,415	3,323	1,414	415	265
Contract manufacturer	419	257	109	32	20
Specification developer	541	352	162	27	0
Repacker/relabeler	828	538	248	41	0
Contract sterilizer	34	22	10	2	0
Total	7,237	4,492	1,943	517	285

[1] Based on data from FDA's Registration and Listing Branch, 1992, adjusted to reflect 13 percent not required to register and 6 percent exempt from CGMP requirements.
[2] ERG, Section 3.

TABLE 2.—DISTRIBUTION OF ESTABLISHMENTS BY HIGHEST CLASS OF MEDICAL DEVICE MANUFACTURED

Type of establishment	Total [1]	Class [2]			Noncritical	Critical
		I	II	III		
Manufacturer	5,415	1,137	3,844	433	4,873	541
Contract manufacturer	419	88	297	33	377	42
Specification developer	541	114	384	43	487	54
Total	6,375	1,339	4,525	510	5,737	637

[1] Includes manufacturing and product development establishments only.
[2] The Evolving Medical Device Industry 1976 through 1984. OPE, FDA (OPE study 74).
Note: Totals may not add due to rounding.

TABLE 3.—Annual Number of 510(K) AND PMA SUBMISSIONS PER ESTABLISHMENT

	Total	Employment size			
		Small (1–19)	Medium (20–99)	Large (100–249)	Very large (≥250)
Average number of product submissions	[1] 6,317	2,264	885	1,342	1,826
Number of affected establishments	[2] 5,956	3,675	1,576	442	265
Average number of 510(k) and PMA submissions per establishment	1.1	0.6	0.6	3.0	6.9

[1] Number includes 50 percent of PMA supplements.
[2] The number of manufacturers and the number of specification developers that would incur design costs associated with new product introduction.
Source: ERG, Section 3.

TABLE 4.—TOTAL COMPLIANCE COSTS BY MOST COSTLY INCREMENTAL TASKS

[$ millions]

Incremental tasks	One-time annualized [1]	Annual		Total annualized
		Labor	Nonlabor	
Preproduction design:				
Design verification	NA	19.7	29.5	49.2
Design review	NA	6.4	NA	6.4
Design changes	0.1	3.9	NA	4.0
Design and development planning	0.9	1.6	NA	2.5
Other:				
Quality audit	0.5	4.7	NA	5.2
Purchasing controls	0.6	4.7	2.6	7.9
Management review	NA	2.2	NA	2.2
Corrective action	0.9	0.3	NA	1.2
All remaining	3.3	2.0	0.5	5.9
Total of proposed regulation	6.3	45.5	32.6	84.5

[1] One-time costs annualized over 5 years at discount rate of 10 percent.
Notes: NA = Not Applicable; Totals may not add due to rounding; Source: ERG, Section 4.

TABLE 5.—TOTAL ANNUALIZED [1] AVERAGE COSTS PER ESTABLISHMENT BY EMPLOYMENT SIZE

Establishment employment size	Medical and surgical instruments, x-ray, and electromedical device industries (SIC 3841, 3842, 3844, and 3845) (dollars)	Dental and ophthalmic industries (SIC 3843 and 3851) (dollars)
Small (1–19)	19,300	7,700
Medium (20–99)	15,800	8,700
Large (100–249)	27,800	16,300
Very large (≥ 250)	11,600	11,600
All establishments	18,700	8,800

[1] One-time costs annualized over 5 years at discount rate of 10 percent.
Source: ERG, Section 6.

TABLE 6.—TOTAL ANNUALIZED COSTS BY SIZE CATEGORY

[$ millions]

Establishment size	One-time annualized [1]	Annual		Total annualized
		Labor	Nonlabor	
Small (1–19)	3.2	26.0	21.0	50.2
Medium (20–99)	2.0	11.3	7.7	21.0
Large (100–249)	0.7	5.8	3.8	10.2
Very large (≥ 250)	0.5	2.5	0.1	3.1
All establishments	6.3	45.6	32.6	84.5

[1] One-time costs annualized over 5 years at discount rate of 10 percent.
Notes: Totals may not add due to rounding; Source: ERG, Section 4.

TABLE 7.—NUMBER OF DESIGN-RELATED REPORTS AND ESTIMATED AVOIDED DEATHS AND SERIOUS INJURIES

	Fatalities			Serious injuries		
	Class II	Class III	Total	Class II	Class III	Total
Number in 1991	551	482	1,033	4,269	12,175	16,444
Device-related	124	76	200	538	3,214	3,752
Design-related [1]	37	23	60	161	964	1,126
Adjusted total number of design-related MDR's [2]	45	27	72	226	1,350	1,576
Number avoided	33	20	53	165	984	1,149

[1] Assumes 30 percent of device-related MDR's are design-related, based on FDA recall data.
[2] Total number of fatalities and injuries increased by 20 and 40 percent, respectively, to adjust for underreporting.
Source: ERG, Section 5.

TABLE 8.—NUMBER OF AVOIDED DESIGN-RELATED RECALL EVENTS BY CLASS OF DEVICE

Device Class	Average number of design-related recall events [1]	Number of avoided design-related recall events [2]
I	16	NA
II	79	58
III	12	9
All devices	107	67

[1] Office of Compliance and Surveillance, CDRH.
[2] ERG estimates based on random sample of recent design-related recalls.

TABLE 9.—TOTAL ANNUALIZED [1] COST BY DEVICE CLASS FOR PROPOSAL AND ALTERNATIVE

[$ millions]

Device class	Proposal		Alternative	
	Annualized costs	Percent of total	Annualized costs	Percent of total
Class I	5.2	6	11.9	13
Class II	71.4	85	71.4	78
Class III	7.9	9	7.9	9

TABLE 9.—TOTAL ANNUALIZED [1] COST BY DEVICE CLASS FOR PROPOSAL AND ALTERNATIVE—Continued

[$ millions]

Device class	Proposal		Alternative	
	Annualized costs	Percent of total	Annualized costs	Percent of total
Total	84.5	100	91.3	100

[1] One-time costs annualized over 5 years at discount rate of 10 percent
Source: ERG, Section 4.

TABLE 10.—NUMBER OF DESIGN-RELATED REPORTS AND ESTIMATED AVOIDED DEATHS AND SERIOUS INJURIES WHEN ALL DEVICES ARE SUBJECT TO DESIGN CONTROLS

	Fatalities				Serious injuries			
	Class I	Class II	Class III	Total	Class I	Class II	Class III	Total
Number in 1991	38	551	482	1,071	1,092	4,269	12,175	17,536
Device-related	1	124	76	201	355	538	3,214	4,107
Design-related [1]	<1	37	23	60	106	161	964	1,232
Adjusted total number of design-related MDR's [2]	<1	45	27	72	148	226	1,350	1,725
Number avoided	<1	33	20	53	108	165	984	1,257

[1] Assumes 30 percent of device-related MDR's are design-related, based on FDA recall data.
[2] Total number of fatalities and injuries increased by 20 and 40 percent, respectively, to adjust for underreporting.

TABLE 11.—NUMBER OF AVOIDED DESIGN-RELATED RECALL EVENTS BY CLASS OF DEVICE WHEN ALL DEVICES ARE SUBJECT TO DESIGN CONTROLS

Device class	Average number of design-related recall events [1]	Number of avoided design-related recall events [2]
I	16	11
II	79	58
III	12	9
All devices	91	78

[1] Office of Compliance and Surveillance, CDRH.
[2] ERG estimates based on random sample of recent design-related recalls.
Source: ERG, Section 5.

TABLE 12.—MAXIMUM POTENTIAL IMPACT ON PRICE OR PROFITS BY INDUSTRY AND EMPLOYMENT SIZE

Industry	Total annualized compliance costs as a percentage of shipments	After-tax compliance costs as a percentage of after-tax income
3841 Surgical and medical instruments	0.15	2.41
3842 Surgical appliances and supplies	0.18	2.29
3843 Dental equipment and supplies	0.24	3.02
3844 X-ray apparatus and tubes	0.06	1.10
3845 Electromedical equipment	0.06	0.88
3851 Ophthalmic goods	0.20	3.00
All	0.15	2.11
Establishment size:		
Small (1–19)	1.78	NA
Medium (20–99)	0.23	NA
Large (100–249)	0.11	NA
Very large (≥250)	0.01	NA
All	0.15	NA

Notes: NA=not available; Source: ERG, Section 5.

VIII. Paperwork Reduction Act of 1980

This proposed rule contains information collections that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1980 (44 U.S.C. chapter 35). The title, description, and respondents of the information collection are shown below with an estimate of the annual recordkeeping burden.

Title: Medical Devices, Current Good Manufacturing Practice Regulations,

Proposed Revisions, Request for Comments.

Description: FDA is proposing to revise the CGMP regulations for medical devices in part 820. Changes proposed include revisions that would: Replace quality assurance program requirements with quality system requirements, including design, procurement and servicing controls; eliminate critical component and critical operation terminology; expand procedures for device failure and complaint investigations; clarify requirements to qualify, verify, and validate processes and changes; and, clarify requirements to evaluate quality data and correct quality problems. Through reorganization and modification of terms, the revised CGMP requirements for medical devices are compatible with specifications for quality systems contained in international quality standards, ISO 9001/EN 29001, "Quality Systems Part 1. Specification for design/development, production, installation and servicing."

Description of Respondents: Businesses or other for-profit and small businesses or organizations.

ESTIMATED ANNUAL BURDEN FOR RECORDKEEPING

Part	Annual no. of recordkeepers	Annual hours per recordkeeper	Total recordkeeping hours
820	7,237	55.880842	404,410

Under OMB information collection No. 0910–0073, an estimated 375,266 burden hours have already been approved for 21 CFR part 820. The information requirements contained in this proposed rule will add 463,128 hours to the burden estimate.

As required by section 3504(h) of the Paperwork Reduction Act, FDA is submitting to OMB a request that it approve these information collection requirements. Organizations and individuals desiring to submit comments for consideration by OMB on these information collection requirements, should direct them to FDA's Dockets Management Branch (address above) and to the Office of Information and Regulatory Affairs, Office of Management and Budget, rm. 3001, New Executive Office Bldg., 725 17th St. NW., Washington, DC 20503, Attn: Desk Officer for FDA.

IX. References

The following references have been placed on display in the Dockets Management Branch (address above) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. ISO 9001/EN 29001 "Quality Systems Part 1. Specification for Design/Development, Production, Installation, and Servicing," International Organization for Standardization, 1987.

2. "Suggested Changes to the Medical Device Good Manufacturing Practices Regulation Information Document November 1990," FDA, Center for Devices and Radiological Health, Rockville, MD 20857, Docket No. 90N–0172.

3. "Device Recalls: A Study of Quality Problems," FDA, Center for Devices and Radiological Health, Rockville, MD 20857, HHS Publication FDA 90–4235, January 1990.

4. "Preproduction Quality Assurance Planning; Recommendations for Medical Device Manufacturers," FDA, Center for Devices and Radiological Health, Rockville, MD 20857, HHS Publication FDA 90–4236, September 1989.

5. "Software Related Recalls for Fiscal Years FY 83–FY 91," FDA, Center for Devices and Radiological Health, Rockville, MD 20857, May 1992.

6. "FDA Medical Device Regulation From Premarket Review to Recall," Office of Inspector General, Washington, DC, HHS Publication OEI 09–90–00040, February 1991.

7. Letter from American Cyanamid Company to Dockets Management Branch (HFA–305), in response to Docket No. 90N–0172, February 28, 1991.

8. Letter from XRE Corporation to Dockets Management Branch (HFA–305) in response to Docket No. 90N–0172, August 16, 1990.

9. "Guideline on General Principles of Process Validation," FDA, Center for Drugs and Biologics, and Center for Devices and Radiological Health, Rockville, MD 20857, May 1987.

10. EN46001 "Quality Systems—Medical Devices—Particular Requirements for the Application of EN29001."

11. EN46002 "Quality Systems—Medical Devices—Particular Requirements for the Application of EN29002."

12. ISO 8402 "Quality Vocabulary," International Organization for Standardization, 1986.

13. "Management Practices; U.S. Companies Improve Performance Through Quality Efforts," General Accounting Office, Washington, DC 20548, May 1991, GAO/NSLAD–91–190.

14. "Economic Analysis of Proposed Revisions to the Good Manufacturing Practices Regulation for Medical Devices," FDA Contract No. 223–91–8100, Eastern Research Group, Inc., Lexington, MA 02173.

X. Request for Comments

Interested persons may, on or before February 22, 1993, submit to the Dockets Management Branch (address above) written comments regarding this proposal. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

FDA is establishing a 120-day comment period, rather than its usual 60 days, in anticipation that the agency will be requested to extend the comment period. The agency will not entertain requests to extend the comment period further.

List of Subjects in 21 CFR Part 820

Medical devices, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, it is proposed that 21 CFR part 820 be revised to read as follows:

PART 820—GOOD MANUFACTURING PRACTICE FOR MEDICAL DEVICES

Subpart A—General Provisions

Sec.

820.1 Scope.
820.3 Definitions.
820.5 Quality system.

Subpart B—Quality System Requirements

820.20 Management responsibility.
820.22 Quality audit.
820.25 Personnel.

Subpart C—Design Controls

820.30 Design controls.

Subpart D—Document and Record Controls

820.40 Document controls.

Subpart E—Purchasing Controls

820.50 Purchasing controls.

Subpart F—Identification and Traceability

820.60 Identification and traceability.
820.65 Critical devices, traceability.

Subpart G—Production and Process Controls

820.70 Production and process controls.
820.75 Special processes.

Subpart H—Inspection and Testing

820.80 Inspection and testing.
820.84 Inspection, measuring, and test equipment.
820.86 Inspection and test status.

Subpart I—Nonconforming Components and Devices

820.90 Nonconforming components and devices.
820.91 Nonconforming components and devices, critical devices.

Subpart J—Corrective Action

820.100 Corrective action.

Subpart K—Handling, Storage, Distribution, and Installation

820.120 Handling.
820.122 Storage.
820.124 Distribution.
820.126 Installation.

Subpart L—Packaging and Labeling Control

820.160 Device packaging.
820.162 Device labeling.
820.165 Critical devices, labeling.

Subpart M—Records

820.180 General requirements.
820.181 Device master record (DMR).
820.184 Device history record.
820.198 Complaint files.

Subpart N—Servicing

820.200 Servicing.

Subpart O—Statistical Techniques

820.250 Statistical techniques.

Authority: Secs. 501, 502, 510, 513, 514, 515, 518, 519, 520, 522, 701, 704, 801, 803 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351, 352, 360, 360c, 360d, 360e, 360h, 360i, 360j, 360l, 371, 374, 381, 383).

Subpart A—General Provisions

§ 820.1 Scope.

(a) *Applicability.* (1) The regulations set forth in this part describe current good manufacturing practices (CGMP's) for methods used in, and the facilities and controls used for, the design, purchasing, manufacture, packaging, labeling, storage, installation, and servicing of all finished devices intended for human use. The regulations in this part are intended to ensure that finished devices will be safe and effective and otherwise in compliance with the Federal Food, Drug, and Cosmetic Act (the act). This part establishes minimum requirements applicable to manufacturers of finished devices, including additional requirements for critical devices. With respect to class I devices, design controls apply only to those devices listed in § 820.30(a)(2). The regulations in this part do not apply to manufacturers of components or parts of finished devices when such components or parts are not intended specifically for use as part of a medical device, but such manufacturers are encouraged to use appropriate provisions of this regulation as guidelines. Manufacturers of human blood and blood components are not subject to this part, but are subject to part 606 of this chapter.

(2) The provisions of this part shall be applicable to any finished device, as defined in this part, intended for human use, that is manufactured, imported, or offered for import in any State or Territory of the United States.

(b) *Limitations.* The CGMP regulation in this part supplements regulations in other parts of this chapter except where explicitly stated otherwise. In the event it is impossible to comply with all applicable regulations, both in this part and in other parts of this chapter, the regulations specifically applicable to the device in question shall supersede any other regulations.

(c) *Consequences of failure to comply with the regulations.* (1) The failure to comply with any applicable provision in this part in the design, purchasing, manufacture, packaging, labeling, storage, installation, or servicing of a device renders the device adulterated under section 501(h) of the act. Such a device, as well as any person responsible for the failure to comply, is subject to regulatory action under sections 301, 302, 303, 304, and 801 of the act.

(2) If a manufacturer who imports devices into the United States refuses to schedule an FDA inspection of a foreign facility for compliance with this part or refuses to permit FDA to conduct or complete a scheduled inspection at a foreign facility, it shall appear, for purposes of 801(a) of the act, that the methods used in, and the facilities and controls used for, the design, purchasing, manufacture, packaging, labeling, storage, installation, or servicing of any devices produced at such facility that are offered for import into the United States do not conform to the requirements of section 520(f) of the act and this part and that the devices manufactured at that facility are adulterated under section 501(h) of the act. Foreign CGMP inspections will be scheduled in advance by FDA in writing.

(d) *Exemptions or variances.* Any person who wishes to petition for an exemption or variance from any device good manufacturing practice requirement is subject to the requirements of section 520(f)(2) of the act. Petitions for an exemption or variance shall be submitted according to the procedures set forth in § 10.30 of this chapter, the Food and Drug Administration's administrative procedures. Guidance is available from the Center for Devices and Radiological Health, Division of Small Manufacturers Assistance, Regulatory Assistance Branch (HFZ–220), 1901 Chapman Ave., Rockville, MD 20857, telephone 1–800–638–2041. Maryland and foreign residents, 1–301–443–6597, FAX 301–443–8818.

§ 820.3 Definitions.

(a) *Act* means the Federal Food, Drug, and Cosmetic Act, as amended (secs. 201–903, 52 Stat. 1040 et seq., as amended (21 U.S.C. 321–394)). All definitions in section 201 of the act shall apply to these regulations.

(b) *Complaint* means any written, electronic, or oral communication that relates to or concerns the unacceptability of the identity, quality, durability, reliability, safety, effectiveness, or performance of a device.

(c) *Component* means any raw material, substance, piece, part, software, firmware, packaging, labeling, or assembly used during device manufacture which is intended to be included as part of the finished, packaged, and labeled device.

(d) *Control number* means any distinctive combination of letters or numbers, or both, from which the complete history of the purchasing, manufacturing, packaging, labeling, and distribution of a lot or batch of finished devices can be determined.

(e) *Critical device* means a device that is intended to be surgically implanted into the body or to support or sustain life the failure of which to perform when properly used in accordance with instructions for use provided in the labeling can be reasonably expected to result in a serious injury to the user. Examples of critical devices are identified by the Commissioner of Food and Drugs after consultation with the Device Good Manufacturing Practice Advisory Committee authorized under section 520(f) of the act, and an illustrative list of critical devices is available from the Center for Devices and Radiological Health, Food and Drug Administration, at the addresses given in § 820.1(d).

(f) *Design history record* means a compilation of records containing the complete design history of a finished device.

(g) *Design input* means the physical and performance requirements of a device that are used as a basis for device design.

(h) *Design output* means the results of a design effort at each design phase and at the end of the total design effort. The total finished design output consists of the device, its packaging and labeling, and the associated specifications and drawings and the production and quality system specifications and procedures which are included in the device master record (DMR).

(i) *Design review* means a comprehensive, systematic examination of a design to evaluate the adequacy of the device requirements, to evaluate the capability of the design to meet these requirements, and to identify problems with the design and design requirements and to propose solutions to all such problems.

(j) *Device history record* means a compilation of records containing the complete production history of a finished device.

(k) *Device master record (DMR)* means a compilation of records containing a device's complete design, formulation, and specifications, the purchasing and manufacturing procedures and specifications, the quality system requirements and procedures, and the packaging, labeling, servicing, maintenance, and installation procedures of a finished device.

(l) *Establish* means define, document, and implement.

(m) *Executive management* means those senior employees of a manufacturer who have the authority to establish or make changes to the manufacturer's quality policy, quality system requirements, or to a device's design specifications or its production, distribution, servicing, maintenance, or installation procedures.

(n) *Finished device* means any device or accessory to any device that is suitable for use, whether or not it is packaged or labeled for commercial distribution. A finished device includes a device that is intended to be sterile that is not yet sterilized.

(o) *Lot or batch* means a unit of components or finished devices that consists of a single type, model, class, size, composition, and software version that are manufactured under essentially the same conditions and that are intended to have uniform character and quality within specified limits.

(p) *Manufacturer* means any person who designs, manufactures, fabricates, assembles, or processes a finished device, including contract sterilizers, specification developers, repackers, relabelers, and initial distributors of imported devices.

(q) *Manufacturing material* means any material or substance used in, or to facilitate, a manufacturing process that is not intended by the manufacturer to be included in the finished device, including cleaning agents, mold-release agents, lubricating oils, ethylene oxide or other sterilant residues, or other byproducts of the manufacturing process.

(r) *Nonconforming* means the failure of a component, manufacturing material, or finished device to meet its specifications, either before or after distribution of the finished device.

(s) *Production* means all activities subsequent to design transfer and to the point of distribution.

(t) *Quality* means the totality of features and characteristics that bear on the ability of a device to satisfy fitness-for-use, including safety and performance.

(u) *Quality audit* means an established systematic, independent, examination of a manufacturer's entire quality system that is performed at defined intervals and at sufficient frequency to ensure that both quality system activities and the results of such activities comply with specified quality system procedures, that these procedures are implemented effectively, and that these procedures are suitable to achieve quality system objectives. "Quality audit" is different from, and in addition to, the other quality system activities required by or under this part.

(v) *Quality policy* means the overall quality intentions and direction of an organization with respect to quality, as formally expressed by executive management.

(w) *Quality system* means the organizational structure, responsibilities, procedures, specifications, processes, and resources for implementing quality management.

(x) *Record* means any written or automated document, including specifications, procedures, protocols, standards, methods, instructions, plans, files, forms, notes, reviews, analyses, and reports.

(y) *Reprocessing* means all or part of a manufacturing operation which is intended to correct nonconformance in a component or finished device.

(z) *Servicing* means maintenance or repair of a finished device for purposes of returning a device to its specifications.

(aa) *Special process* means any process the results of which cannot be completely verified by subsequent inspection and testing.

(bb) *Specifications* means the documents that prescribe the requirements with which a device, component, production or servicing activity, or quality system must conform.

(cc) *Validation* means, with respect to a device, establishing and documenting evidence that the device is fit for its intended use. With respect to a process, "validation" means establishing and documenting evidence that the process will consistently produce a result or product meeting its predetermined specifications and quality attributes.

(dd) *Verification* means confirming and documenting, with valid, objective evidence, that specified requirements have been met. Verification includes the process of examining the results of an activity to determine conformity with the stated specifications for that activity and ensuring that the device is adequate for its intended use.

§ 820.5 Quality system.

Each manufacturer shall establish and maintain a quality system that ensures that the requirements of this part are met, and that devices produced are safe, effective, and otherwise fit for their intended uses. As part of its quality system activities, each manufacturer shall:

(a) Establish effective quality system instructions and procedures in accordance with the requirements of this part; and

(b) Maintain the established quality system instructions and procedures effectively.

Subpart B—Quality System Requirements

§ 820.20 Management responsibility.

(a) *Quality policy.* Each manufacturer's executive management shall establish its policy and objectives for, and commitment to, quality. Executive management shall maintain the policy at all levels in the organization. Executive management shall ensure that this policy is understood by all employees who may affect or influence the quality of a device.

(b) *Organization.* Each manufacturer shall establish and maintain an adequate organizational structure with sufficient personnel to ensure that devices are produced in accordance with the requirements of this part.

(1) Responsibility and authority. With respect to each section in this part, each manufacturer shall establish the responsibility, authority, and interrelation of all personnel who manage, perform, and verify work

affecting quality, particularly for personnel who need the organizational freedom and authority to:

(i) Initiate or implement action to prevent the occurrence or use of nonconforming components, manufacturing materials, or finished devices;

(ii) Identify or document quality problems with devices, production, or the quality system;

(iii) Initiate, recommend, provide, or implement solutions or corrective actions to quality problems;

(iv) Verify the adequacy or implementation of solutions or corrective actions to quality problems; and

(v) Direct or control further processing, distribution, or installation of nonconforming components, manufacturing materials, or finished devices.

(2) Verification resources and personnel. Each manufacturer shall establish verification functions and shall provide adequate resources and assign adequately trained personnel to perform verification activities.

(3) Management representative. Each manufacturer's executive management shall appoint an individual in executive management, who irrespective of other responsibilities, shall have established authority over and responsibility for:

(i) Ensuring that quality system requirements are established and maintained in accordance with this part; and

(ii) Reporting on the performance of the quality system to executive management for review and to provide information for improvement of the quality system; and the appointment shall be documented.

(c) *Management review.* Each manufacturer's executive management shall review the suitability and effectiveness of the quality system at defined intervals and at sufficient frequency to ensure that the quality system satisfies the requirements of this part and the manufacturer's established quality policy objectives. The management review shall be conducted in accordance with established review procedures, and the results of each quality system review shall be documented.

§ 820.22 Quality audit.

(a) Each manufacturer shall conduct quality audits to verify that the quality system is in compliance with the established quality system requirements. Quality audits shall be conducted in accordance with established audit procedures by appropriately trained individuals who do not have direct responsibilities for the matters being audited. A report of the results of each quality audit shall be made and the audit reports shall be reviewed by management having responsibility for the matters audited. Followup corrective action, including reaudit of deficient matters, shall be taken when necessary and shall be documented in the audit report.

(b) Section 820.180 does not apply to quality audit reports required under this section, except reports written to satisfy § 820.50(a), but does apply to established quality audit procedures. Audit reports written as part of the assessment of suppliers or contractors (§ 820.50(a)) are subject to review and copying by FDA. Upon request of a designated employee of the Food and Drug Administration, an employee in executive management shall certify in writing that the audits of the quality system required under this section have been performed and documented and that any required corrective action has been taken.

§ 820.25 Personnel.

(a) *General.* Each manufacturer shall employ sufficient personnel with the necessary education, background, training, and experience to ensure that all activities required by this part are correctly performed.

(b) *Training.* Each manufacturer shall ensure that all personnel are trained to adequately perform their assigned responsibilities. Training shall be conducted in accordance with established procedures by qualified individuals to ensure that employees have a thorough understanding of their current job functions and with the CGMP requirements applicable to their job functions. As part of their training, all employees shall be made aware of device defects which may occur from the improper performance of their specific jobs. Personnel who perform verification activities shall be made aware of defects and errors that may be encountered as part of their verification functions. Employee training shall be documented.

(c) *Consultants.* (1) Each manufacturer shall ensure that any consultant advising on the methods used in, or facilities or controls used for, the design, purchasing, manufacture, packaging, labeling, storage, installation, or servicing of devices has sufficient qualifications (education, training, and experience) to advise on the subjects about which the consultant will advise.

(2) Each manufacturer shall maintain records pertaining to each consultant. Such records shall include the consultant's name and address, the consultant's qualifications, including a copy of the curriculum vitae and a list of previous jobs, and a specific description of the subjects on which the consultant advised.

Subpart C—Design Controls

§ 820.30 Design controls.

(a) *General.* (1) Each manufacturer of any class III, or class II device, and the class I devices listed in paragraph (a)(2) of this section shall establish and maintain procedures to control and verify the design of the device in order to ensure that specified design requirements are met.

(2) The following class I devices are subject to design controls:

Section	Device
862.2050 through 862.2920.	Instruments, Clinical Laboratory.
868.6810	Catheter, Tracheobronchial Suction.
878.4460	Glove, Surgeon's.
880.4680	Apparatus, Single Patient, Portable Suction.
880.6760	Restraint, Protection.
892.1100	Camera, Scintillation (gamma).
892.1110	Camera, Positron.
892.1130	Counter, Whole Body, Nuclear.
892.1300	Scanner, Rectilinear, Nuclear.
892.1320	Probe, Uptake, Nuclear.
892.1330	Scanner, Rectilinear, Nuclear.
892.1410	Synchronizer, Electrocardiograph, Nuclear.
892.1970	Synchronizer, Radiographic, ECG/Respirator.
892.5650	System, Applicator, Radionuclide, Manual.
892.5740	Source, Radionuclide, Teletherapy.

(b) *Design and development planning.* Each manufacturer shall establish and maintain plans that identify each design and development activity and the persons responsible for each activity. The plans shall describe or reference the description of these design and development activities, including any interaction between or among different organizational and technical groups. The plans shall be updated as design and development evolves.

(c) *Design input.* Each manufacturer shall establish design input requirements relating to a device. The design input requirements shall completely address the intended use of the device, including the needs of the user and patient, and shall be reviewed and approved by a designated qualified individual. The approval of design input requirements, including the date and the person(s) approving the requirements, shall be documented.

(d) *Design verification.* Each manufacturer shall establish and maintain procedures for verification of the device design and assign such functions to competent personnel. Design verification shall be performed in a timely manner and shall confirm that design output meets the design input requirements and that the design is adequate for its intended use. The results of the design verification, including identification of the design verified, verification method(s), the date, and the person(s) performing the verification shall be documented in the design history record. Where applicable, design verification shall include software validation and hazard analysis.

(e) *Design review.* Each manufacturer shall conduct a formal design review of the design output according to established procedures. Each manufacturer shall assign design review responsibility to qualified individuals who do not have direct responsibility for the design development. The assignments shall be documented. The results of a design review shall be documented in the design history record.

(f) *Design output.* Each manufacturer shall define and document design output in terms that allow an adequate evaluation of conformance to design input requirements. Design output shall meet the design input requirements and shall include those design characteristics that are essential for the intended use of the device.

(g) *Design transfer.* Each manufacturer shall establish and maintain procedures to ensure that the design basis for a device and its components are correctly translated into production specifications. The production specifications shall be approved by an individual designated by the manufacturer. The approval, including identification of the design, the date, and the person(s) approving the specifications, shall be documented. Each manufacturer shall select a representative sample of a device from the first three production lots or batches and test such sample under actual or simulated use conditions. Each manufacturer shall conduct such testing according to established procedures and shall maintain records of all results of the testing. Each manufacturer shall also conduct such testing when changes are made in the device or manufacturing process.

(h) *Design release.* Each manufacturer shall ensure that a design is not released for production until the design is approved by individuals designated by the manufacturer. The designated individuals shall review all records required for the design history record to ensure that the design history file is complete and that the final design is consistent with the approved design plan before releasing the design. The release, including the date and signature of the individual(s) approving release, shall be documented.

(i) *Design changes.* Each manufacturer shall establish and maintain procedures for the identification, documentation, validation, review, and approval of design changes.

(j) *Design history record.* Each manufacturer shall establish and maintain a design history record for each device. Each design history record shall contain or reference all records necessary to demonstrate that the design was developed in accordance with the approved design plan and the requirements of this part.

Subpart D—Document and Record Controls

§ 820.40 Document controls.

Each manufacturer shall establish and maintain document control procedures to ensure that all documents that must be established and maintained under this part meet the requirements of this part and are accurate and adequate for their intended use.

(a) *Document approval and issue.* Each manufacturer shall designate individuals to review and approve all documents established under this part for adequacy prior to issuance. The approval, including the date and signature of the individual(s) approving the document, shall be documented.

(b) *Document distribution.* Each manufacturer shall ensure that all documents are current and available at all locations for which they are designed, and that all unneeded or obsolete documents are removed from all points of use in a timely manner.

(c) *Documentation changes.* Changes to specifications, methods, or procedures for components, finished devices, manufacturing materials, production, installation, servicing, or the quality system shall be documented, reviewed, and approved by individuals in the same functions/organizations that performed the original review and approval unless specifically designated otherwise. In addition, any change to a specification, method, or procedure that may affect quality shall be validated as adequate for their intended use before approval and issuance. Validation results shall be recorded. Approved changes shall be communicated to the appropriate personnel in a timely manner. When changes are made to a specification, method, or procedure, each manufacturer shall evaluate the change in accordance with an established procedure to determine if the submission of a premarket notification (510(k)) under § 807.81(a)(3) of this chapter, or the submission of a supplement to a premarket approval application (PMA) under § 814.39(a) of this chapter is required, as applicable. Records of this evaluation and its results shall be maintained.

(d) *Documentation change records.* Each manufacturer shall maintain records of changes to documents. Documentation change records shall include a description of the change, identification of the affected documents, the signature of the approving individuals, the approval date, and the date the change becomes effective. A list, index, or equivalent document control procedure shall be established and maintained to identify the current revision of documents in order to ensure that only current, approved documents are in use.

Subpart E—Purchasing Controls

§ 820.50 Purchasing controls.

Each manufacturer shall establish and maintain procedures to ensure that all components, manufacturing materials, and finished devices that are manufactured, processed, labeled, or packaged by other persons or held by other persons under contract conform to specifications. Each manufacturer shall also ensure that services provided by other persons conform to specifications.

(a) *Assessment of suppliers and contractors.* Each manufacturer shall establish and maintain assessment criteria for suppliers and contractors that specify the requirements, including quality requirements that suppliers and contractors must meet. Each manufacturer shall assess and select potential suppliers and contractors on the basis of their ability to meet requirements, including quality requirements and shall establish and maintain a list of suppliers and contractors that meet the manufacturer's documented assessment criteria. Records of the assessment, and assessment results shall be maintained.

(b) *Purchasing forms.* Each manufacturer shall establish and maintain purchasing forms that clearly describe or reference the specifications, including quality requirements, for the components, manufacturing materials, finished devices, or services ordered or contracted for. Purchasing forms shall include an agreement that the suppliers agree to notify the manufacturer of any changes in the product or service so that manufacturers may determine whether

the change may affect the quality of a finished device. Each manufacturer shall review and approve purchasing documents prior to release. The approval, including the date and signature of the individual(s) approving the form, shall be documented.

Subpart F—Identification and Traceability

§ 820.60 Identification and traceability.

Each manufacturer shall establish and maintain procedures for identifying components, manufacturing materials, and finished devices during all stages of production, distribution, and installation to prevent mixups and to ensure orderly handlings. For certain devices, additional traceability requirements apply under section 519(e) of the act and part §§ 820.65 and 820.165 of this chapter.

§ 820.65 Critical devices, traceability.

Each manufacturer shall identify each unit, batch, or lot of critical devices with a control number. Such identification shall be recorded in the device history record.

Subpart G—Production and Process Controls

§ 820.70 Production and process controls.

(a) *General.* Each manufacturer shall design, conduct, and control all production processes to ensure that a device conforms to its specifications. Where any deviation from device specifications could occur as a result of the manufacturing process, the manufacturer shall establish and maintain process control procedures that describe all process controls necessary to ensure conformance to specifications. Process controls shall include:

(1) Documented instructions, standard operating procedures (SOP's), and methods that define and control the manner of production, installation, and servicing;

(2) Monitoring and control of process parameters and component and device characteristics during production, installation, and servicing;

(3) Compliance with applied reference standards or codes and process control procedures;

(4) The approval of processes and process equipment; and

(5) Criteria for workmanship which shall be expressed in documented standards or by means of representative samples.

(b) *Environmental control.* Each manufacturer shall establish and maintain a control system to prevent contamination or other adverse effects on the device and to provide proper conditions for all operations. Conditions to be considered for control include: Lighting, ventilation, space, temperature, humidity, air pressure, filtration, airborne contamination, static electricity, and other environmental conditions. Each manufacturer shall periodically inspect its facilities and review its control system to verify that the system is adequate and functioning properly. Records of the results of such inspections shall be made and reviewed.

(c) *Cleaning and sanitation.* Each manufacturer shall establish and maintain adequate cleaning procedures and schedules to meet manufacturing process specifications. Each manufacturer shall ensure that the appropriate personnel understand such procedures.

(d) *Personnel health and cleanliness.* Each manufacturer shall ensure that personnel in contact with a device or its environment are clean, healthy, and suitably attired where lack of cleanliness, good health, or suitable attire could adversely affect the device. Any person who appears to be unclean or inappropriately attired shall be excluded from operations until he or she is clean and suitably attired. Any person who, by medical examination or supervisory observation, appears to have a condition which could adversely affect the device shall be excluded from operations until the condition is corrected. Each manufacturer shall instruct personnel to report such conditions to their supervisors.

(1) Clothing. When special clothing requirements are necessary to ensure that a device is fit for its intended use, each manufacturer shall provide clean dressing for personnel.

(2) Hygiene. Each manufacturer shall provide clean and adequate washing and toilet facilities.

(3) Personnel practices. When eating, drinking, smoking, and other activities by personnel may have an adverse effect on a device, each manufacturer shall limit such practices to designated areas. Each manufacturer shall ensure that its personnel understand any such limits. Each manufacturer shall designate selected areas to avoid any adverse effects on a device.

(e) *Contamination control.* Each manufacturer shall establish and maintain procedures to prevent contamination of equipment, components, manufacturing materials, and in-process and finished devices by rodenticides, insecticides, fungicides, fumigants, cleaning and sanitizing substances, and hazardous substances, including hazardous substances or contaminants generated by the manufacturing process.

(f) *Sewage and refuse disposal.* Each manufacturer shall dispose of sewage, trash, byproducts, chemical effluents, and other refuse in a safe, timely, and sanitary manner.

(g) *Equipment.* Each manufacturer shall ensure that all equipment used in the manufacturing process is adequate for its intended use and is appropriately designed, constructed, placed, and installed to facilitate maintenance, adjustment, cleaning, and use.

(1) Maintenance schedule. Each manufacturer shall establish and maintain schedules for the maintenance, adjustment, and, where applicable, cleaning of equipment to ensure that manufacturing specifications are met. The maintenance schedule shall be visibly posted on or near each piece of equipment or shall be readily available to personnel performing maintenance activities. A written record shall be maintained documenting the date when scheduled maintenance activities were performed and the individual(s) performing the maintenance activity.

(2) Inspection. Each manufacturer shall conduct periodic inspections in accordance with established procedures to ensure adherence to applicable equipment maintenance schedules. The inspections, including the date and individual conducting the inspections, shall be documented.

(3) Adjustment. Each manufacturer shall ensure that any inherent limitations or allowable tolerances are visibly posted on or near equipment requiring periodic adjustments or are readily available to personnel performing these adjustments.

(4) Manufacturing material. Each manufacturer shall establish and maintain procedures for the use and removal of manufacturing material to ensure that such material is removed from the device or limited to a specified amount that does not adversely affect the device's quality. The removal of such manufacturing material shall be documented.

(h) *Automated processes.* When computers are used as part of production, the quality system, or automated data processing systems, individuals designated by the manufacturer shall validate the computer software according to an established protocol. The results shall be documented. All software changes shall be made by a designated individual(s) through an established validation and approval procedure in accordance with § 820.40(c) document changes.

§ 820.75 Special processes.

(a) Each manufacturer shall ensure that special processes are:

(1) Validated according to an established protocol and records shall be made of the results of validation, including the date of and individual responsible for the validation;

(2) Conducted according to established procedures that describe all processing controls necessary to ensure conformance to specifications;

(3) Monitored according to establish procedures to ensure process parameters are met; and

(4) Performed by qualified, designated individuals.

(b) The individual(s) responsible for the performance of a special process shall record the completion of the process in the device history record. The record shall include identification of the process, the date performed, each individual that performed the special process, and the equipment used.

Subpart H—Inspection and Testing

§ 820.80 Inspection and testing.

(a) *General.* Each manufacturer shall establish and maintain the inspection and testing activities necessary to ensure that specified requirements are met. The results of all inspection and testing shall be documented.

(b) *Receiving inspection and testing.* Each manufacturer shall establish and maintain procedures for acceptance of incoming components, manufacturing materials, and finished devices. Incoming components, manufacturing materials, and finished devices shall not be used or processed until they have been verified as conforming to specified requirements. Individual(s) designated by the manufacturer shall accept or reject incoming components, finished devices, and manufacturing materials. Acceptance and rejection shall be documented.

(c) *In-process inspection and testing.* Each manufacturer shall establish and maintain procedures for inspecting and testing in-process components, finished devices, and manufacturing materials. Each manufacturer shall establish and maintain procedures for holding in-process components, finished devices, and manufacturing materials until the required inspection and tests have been completed or necessary reports have been received and verified.

(d) *Final inspection and testing.* Each manufacturer shall establish and maintain procedures for finished device inspection to ensure each lot or batch meets device specifications. Finished devices shall be held in quarantine or otherwise adequately controlled until released by an individual designated by the manufacturer. Finished devices shall not be released until all the required activities specified in the DMR have been completed and the associated data and documentation are reviewed to ensure all acceptance criteria have been met. Release, including the date and signature of the designated individual(s) responsible for release, shall be documented.

(e) *Inspection and test records.* Each manufacturer shall maintain records of the results of all inspections and tests required by this part. These records shall include the acceptance criteria, inspection checks performed; results; equipment used; and the date and signature of the individual(s) conducting the inspection and testing. These records shall be part of the device history record.

§ 820.84 Inspection, measuring, and test equipment.

Each manufacturer shall ensure that all measurement and test equipment, including mechanical, automated, or electronic inspection and test equipment, is suitable for its intended purposes and is capable of producing valid results. Each manufacturer shall establish and maintain procedures to ensure that equipment is routinely calibrated, inspected, and checked. Records documenting these activities shall be maintained.

(a) *Calibration.* Each manufacturer shall establish and maintain calibration procedures that include specific directions and limits for accuracy and precision and provisions for remedial action when accuracy and precision limits are not met. Calibration shall be performed by personnel who have the necessary education, training, background, and experience.

(b) *Calibration standards.* Each manufacturer shall establish and maintain calibration standards for measurement equipment that are traceable to the national standards of the National Institute for Standards and Technology, Department of Commerce. If national standards are not practical or available, the manufacturer shall use an independent reproducible standard. If no applicable standard exists, the manufacturer shall establish and maintain an in-house standard.

(c) *Calibration records.* Each manufacturer shall ensure that records of calibration dates, the individual performing each calibration, and the next calibration date are maintained. These records shall be maintained by individuals designated by the manufacturer and displayed on or near each piece of equipment or shall be readily available to the personnel using such equipment and the individuals responsible for calibrating the equipment.

(d) *Maintenance.* Each manufacturer shall establish and maintain procedures to ensure that the handling, preservation, and storage of inspection, measuring, and test equipment is such that their accuracy and fitness-for-use are maintained.

(e) *Facilities.* Each manufacturer shall protect inspection, measuring, and test facilities and equipment, including both test hardware and test software, from adjustments that would invalidate the calibration.

§ 820.86 Inspection and test status.

(a) Each manufacturer shall identify the inspection and test status of all components, manufacturing materials, and finished devices. The identification shall be visible, shall indicate the conformance or nonconformance of these items with respect to acceptance criteria, and shall be maintained, as necessary, throughout component acceptance, manufacturing, packaging, labeling, installation, and servicing of the device to ensure that only components, finished devices, and manufacturing materials which have passed the required inspections and tests are distributed, used, or installed.

(b) Each manufacturer shall ensure that records shall identify the individual(s) responsible for the release of components, of manufacturing materials, and of finished devices.

Subpart I—Nonconforming Components and Devices

§ 820.90 Nonconforming components and devices.

(a) *Control of nonconforming components and devices.* Each manufacturer shall establish and maintain procedures to ensure that components, manufacturing materials, finished devices, and returned devices that do not conform to specified requirements are not inadvertently used or installed. The procedures shall provide for the identification, documentation, investigation, segregation, and disposition of nonconforming components, manufacturing materials, finished devices, and returned devices, and for notification of the persons or organizations responsible for the nonconformance.

(b) *Nonconformity review and disposition.* (1) The responsibility for review and the authority for the disposition of nonconforming components, manufacturing materials,

finished devices, and returned devices shall be defined.

(2) Each manufacturer shall establish and maintain procedures for the reprocessing, retesting, and reinspection of nonconforming components and finished devices, to ensure that they meet their original, or subsequently modified and approved, specifications. The procedures shall be contained or referenced in the device master record. Reprocessed devices or components shall be clearly identified as reprocessed, and the reprocessing and reinspection results shall be recorded in the device history record. Reprocessed devices or components shall be subject to another complete reinspection for any characteristic of the device which may be adversely affected by such reprocessing. When there is repeated reprocessing of a device or component, a determination of the effect of the reprocessing upon the device or component shall be made and documented.

Subpart J—Corrective Action

§ 820.100 Corrective action.

(a) Each manufacturer shall establish and maintain procedures for:

(1) Analyzing all processes, work operations, concessions, quality audit reports, quality records, service records, complaints, returned product, and other sources of quality data to identify existing and potential causes of nonconforming components, finished devices, or other quality problems (analysis shall include trend analysis to detect recurring quality problems);

(2) Investigating the failure of any distributed device to meet specifications;

(3) Identifying action needed to correct the cause and prevent recurrence of nonconforming components or finished devices and other quality problems;

(4) Verifying or validating the adequacy of the corrective action to ensure that the corrective action does not adversely affect the finished device and that the corrective action is effective;

(5) Implementing and recording changes in methods and procedures needed as a result of the identification of quality problems and corrective action; and

(6) Ensuring that quality problem information is disseminated to those directly responsible for ensuring quality and is reviewed by management.

(b) All activities required under this section, and their results, shall be documented.

Subpart K—Handling, Storage, Distribution, and Installation

§ 820.120 Handling.

Each manufacturer shall establish and maintain procedures to ensure that mixups, damage, deterioration, or other adverse effects to components, finished devices, and manufacturing materials do not occur during any stage of handling.

§ 820.122 Storage.

(a) Each manufacturer shall establish and maintain procedures for the control of storage areas or stock rooms for components, manufacturing materials, and finished devices to prevent mixups, damage, deterioration, or other adverse effects pending use or distribution.

(b) Each manufacturer shall establish and maintain procedures for authorizing receipt from and dispatch to such designated areas. Any control number or other identification used shall be legible and clearly visible. When the quality of components or finished devices deteriorates over time, such devices shall be stored in a manner to facilitate proper stock rotation and their condition shall be assessed at appropriate intervals. Each manufacturer shall establish and maintain procedures to ensure that all obsolete, rejected, or deteriorated manufacturing materials, components, and devices located in storage are not inadvertently used or distributed.

§ 820.124 Distribution.

(a) Each manufacturer shall establish and maintain procedures for control and distribution of finished devices to ensure that only those devices approved for release are distributed. Where a device's fitness-for-use or quality deteriorates over time, the procedures shall ensure that the oldest approved devices are distributed first and that expired devices are not distributed.

(b) Each manufacturer shall maintain distribution records which include or make reference to the location of:

(1) The name and address of the consignee;

(2) The identification and quantity of devices shipped, the date shipped; and

(3) Any control number used for traceability.

§ 820.126 Installation.

Each manufacturer shall establish and maintain adequate instructions and procedures for proper device installation. Instructions and procedures shall include directions for verifying proper performance of the installation. When a manufacturer or its authorized representative installs a device, the manufacturer or representative shall verify that the device(s) will perform as intended after installation. The results of verification shall be recorded. When a person other than the manufacturer or its authorized representative installs a device, the manufacturer shall ensure that the installation instructions and procedures are distributed with the device or otherwise available to the person installing the device.

Subpart L—Packaging and Labeling Control

§ 820.160 Device packaging.

Each manufacturer shall design and construct device packaging and shipping containers to protect the device from alteration or damage during the customary conditions of processing, storage, handling, and distribution.

§ 820.162 Device labeling.

Each manufacturer shall establish and maintain procedures to maintain labeling integrity and to prevent labeling mixups.

(a) *Labeling integrity.* Each manufacturer shall ensure that labels are designed, printed, and, where applicable, applied so as to remain legible and affixed to the device during the customary conditions of processing, storage, handling, distribution, and use.

(b) *Labeling inspection.* Labels shall not be released for storage or use until a designated individual(s) has examined the labeling for accuracy including, where applicable, the correct expiration date, control number, storage instructions, handling instructions, and additional processing instructions. The release, including the date, name and signature of the individuals performing the examination, shall be documented in the device history record.

(c) *Labeling storage.* Each manufacturer shall store and maintain labeling in a manner that provides proper identification and is designed to prevent mixups.

(d) *Labeling control.* Each manufacturer shall control labeling and packaging operations to prevent labeling mixups.

§ 820.165 Critical devices, labeling.

Labeling for critical devices shall contain a control number.

Subpart M—Records

§ 820.180 General requirements.

All records shall be legible and shall be stored to minimize deterioration, prevent loss, and allow rapid retrieval. All records stored in automated data processing systems shall be backed up. All records required by this part shall be maintained at the manufacturing

establishment or other location that is reasonably accessible to responsible officials of the manufacturer and to employees of the Food and Drug Administration designated to perform inspections. Such records shall be available for review and copying by such employee. Except as specifically provided elsewhere, the following general provisions shall apply to all records required by this part.

(a) *Confidentiality.* Those records deemed confidential by the manufacturer may be marked to aid the Food and Drug Administration in determining whether information may be disclosed under the public information regulation in part 20 of this chapter.

(b) *Record retention period.* All required records pertaining to a device shall be retained for a period of time equivalent to the design and expected life of the device, but in no case less than 2 years from the date of release for commercial distribution by the manufacturer. Photostatic or other reproductions of records required by this part may be used. Where reduction techniques such as microfilming are used, suitable reading and photocopying equipment shall be available for use with the records.

§ 820.181 Device master record (DMR).

Each manufacturer shall maintain device master records (DMR's). Each manufacturer shall ensure that each DMR is prepared, dated, and signed by qualified individual(s) designated by the manufacturer. Any changes in a DMR shall meet the applicable requirements of § 820.40. The DMR for each type of device shall include, or refer to the location of, the following information:

(a) Device specifications including appropriate drawings, composition, formulation, component specifications, software design specifications, and software source code;

(b) Production process specifications including the appropriate equipment specifications, production methods, production procedures, and production environment specifications;

(c) Quality system documents, including verification checks used, the verification apparatus used, and validation protocols and results;

(d) Packaging and labeling specifications, including methods and processes used; and

(e) Installation, maintenance, and servicing procedures and methods.

§ 820.184 Device history record.

Each manufacturer shall maintain device history records. Each manufacturer shall establish and maintain procedures to ensure that device history records are maintained for each batch lot, or unit to demonstrate that the device(s) was manufactured in accordance with the device master record and the requirements of this part. Device history records shall be readily accessible and maintained by a designated individual(s). The device history record shall include, or refer to the location of, the following information:

(a) The dates of manufacture;

(b) The quantity manufactured;

(c) The quantity released for distribution;

(d) The labeling; and

(e) Any control number(s) used.

§ 820.198 Complaint files.

(a) Each manufacturer shall maintain complaint files. Each manufacturer shall establish and maintain procedures for receiving, reviewing, evaluating, and maintaining complaints. Such procedures shall ensure that:

(1) Complaints are received, reviewed, evaluated, investigated, and maintained by a formally designated unit;

(2) Oral complaints are documented upon receipt; and

(3) The complaint is reviewed to determine whether an investigation is necessary. When no investigation is made, the unit shall maintain a record that includes the reason no investigation was made and the name of the individual responsible for the decision not to investigate.

(b) Each manufacturer shall review, evaluate, and investigate all complaints involving the possible failure of a device, labeling, or packaging to meet any of its specifications. Any complaint pertaining to death, injury, or any hazard to safety shall be immediately reviewed, evaluated, and investigated by a designated individual(s) and shall be maintained in a separate portion of the complaint files. Investigations shall include a determination of whether there was an actual device failure to perform pursuant to specifications; whether the device was being used to treat or diagnose a patient; whether a death, injury, or serious illness was involved; and the relationship, if any, of the device to the reported incident or adverse event.

(c) When an investigation is made, a written record of each investigation shall be maintained by the formally designated unit identified in paragraph (a) of this section. The record of investigation shall include:

(1) The name of the device;

(2) The date the complaint was received;

(3) Any control number used;

(4) The name, address, and phone number of the complainant;

(5) The nature of the complaint; and

(6) The results of the investigation.

(d) The investigation results shall include:

(1) The corrective action taken;

(2) The dates of the investigation;

(3) The details of the complaint; and

(4) The reply to the complainant.

(e) When no reply is made to the complainant, the reason shall be recorded.

(f) Records of investigations of events that are determined to be reportable under medical device reporting (MDR) requirements of part 803 of this chapter shall include the information required by part 803 of this chapter. When such information cannot be obtained, a record of the reason shall be made and retained in the record of investigation.

(g) When the formally designated complaint unit is located at a site separate from the actual manufacturing establishment and a complaint involves the manufacturing site, a duplicate copy of the complaint and the record of investigation of the complaint shall be transmitted to and maintained at the actual manufacturing establishment in a file designated for device complaints.

(h) If a manufacturer's formally designated complaint unit is located outside of the United States, a copy of all of each records required under this section shall be maintained in the United States. If a manufacturer has a location in the United States where records are regularly kept, the copies required under this paragraph may be maintained at such location. Otherwise, the copies required under this paragraph shall be provided to and kept by the agent designated under § 803.26(g)(3) of this chapter.

(i) Each manufacturer shall establish and maintain procedures for processing complaints to ensure that all complaints are processed in a uniform and timely manner. Such procedures shall include provisions for determining whether the complaint represents an event which is required to be reported to the Food and Drug Administration under part 803 of this chapter.

(j) Any written or oral complaint that is also a reportable event under part 803 of this chapter shall be identified in the complaint file as such.

Subpart N—Servicing

§ 820.200 Servicing.

Each manufacturer shall establish and maintain procedures to ensure that finished devices that are serviced by the manufacturer or its representatives meet specifications. Procedures for servicing

shall include provisions for determining if service requests represent an event which must be reported to the Food and Drug Administration under the requirements of part 803 of this chapter.

(a) *Service records.* Each manufacturer shall establish and maintain procedures to ensure that service records are maintained that identify the device serviced, including any control number used, the date of service, the service performed, and individual(s) servicing the device.

(b) *Service record evaluation.* Each manufacturer shall analyze servicing records in accordance with § 820.100; except that when a service report involves a death, serious injury, or safety hazard, the report shall be considered a complaint and shall be investigated in accordance with the requirements of § 820.198.

Subpart O—Statistical Techniques

§ 820.250 Statistical techniques.

(a) Where appropriate, each manufacturer shall establish and maintain procedures for identifying valid statistical techniques required for verifying the acceptability of process capability and product characteristics.

(b) Sampling plans shall be written and based on a valid statistical rationale. Each manufacturer shall establish and maintain procedures to ensure that sampling methods are adequate for their intended use and are regularly reviewed, especially for events such as nonconforming devices, adverse quality audit reports, or complaints.

Dated: October 15, 1993.

Michael R. Taylor,

Deputy Commissioner for Policy.

[FR Doc. 93–28554 Filed 11–17–93; 11:07 am]

BILLING CODE 4160–01–P

federal register

Tuesday
November 23, 1993

Part III

General Accounting Office

4 CFR Parts 27 and 28

Personnel Appeals Board; Procedural Regulations; Final Rule

GENERAL ACCOUNTING OFFICE

4 CFR Parts 27 and 28

Personnel Appeals Board; Procedural Regulations

AGENCY: General Accounting Office Personnel Appeals Board.

ACTION: Final rule.

SUMMARY: The General Accounting Office Personnel Appeals Board is revising its procedural regulations. The changes contain several significant refinements of the Board's procedures, clarify the meaning of some sections, correct a few errors in the prior regulations and bring the regulations into conformity with the Civil Rights Act of 1991.

EFFECTIVE DATE: January 1, 1994.

FOR FURTHER INFORMATION CONTACT: Barbara Lipsky, Solicitor for the Personnel Appeals Board, 202–512–6137.

SUPPLEMENTARY INFORMATION: The General Accounting Office Personnel Appeals Board hears and decides cases brought by GAO employees concerning various personnel matters including adverse or performance-based actions, claims of discrimination, alleged prohibited personnel practices and labor-management relations. The Board is revising and reissuing its procedural regulations.

On April 28, 1993, the Board published a notice of proposed rulemaking in the **Federal Register** (58 FR 25785). This notice announced the Board's intention to revise its procedural regulations. It explained how to obtain copies of both the Board's proposed regulations and a detailed statement explaining the changes. Interested persons were invited to submit comments by June 30, 1993. Copies of the proposed regulations, along with the explanation of changes, were also sent to the GAO's Office of General Counsel and to the Board's General Counsel who prosecutes many cases before the Board. The Board's General Counsel, in turn, provided copies to the GAO employee advisory councils. A notice concerning the Board's proposed rulemaking appeared in the "GAO Management News" for the week of May 3–7, 1993 (Vol. 20, No. 30). The Board also sent copies of the proposed changes to all private attorneys who had practiced before the Board in the last five years. The Board received six comments on its proposal. In response to these comments, the Board made several additional changes to its regulations.

All of the changes contained in the Board's proposed regulations (except for minor non-substantive changes in language) were summarized and explained in the explanation of changes that was distributed to interested parties along with the Board's proposal. The Board will not repeat all of that explanatory material here. However, the most significant changes made by the new regulations are highlighted in the next section of this preamble. Following that, the preamble summarizes the more significant comments received by the Board during the comment period and indicates how these comments were addressed in preparing the final version of the regulations.

Highlights of Significant Changes Contained in the New Regulations

The new regulations contain several significant refinements of the Board's prior procedures. The section on initial decisions issued by individual Board members (§ 28.87) has been substantially revised to permit the parties to request that the Board member reconsider his or her decision, and to provide more detailed procedures for appealing the initial decision to the full Board. A new provision in the section on disqualification of judges (§ 28.23) now permits parties to appeal to the full Board if an administrative judge denies a motion requesting that he or she withdraw from the case. Similarly, the full Board is given a greater role in determining whether matters are appropriate for an interlocutory appeal (§ 28.81). The section on requests for stays of personnel actions (§ 28.133) has been revised to provide more detailed procedures for such requests and to provide more specific standards for the disposition of such requests. Section 28.141 has also been revised to provide greater details on the nature of the informal hearing that career appointees may obtain when they are removed from the SES to a GAO position outside the SES for less than fully successful executive performance.

Most of the time limits throughout the regulations have been revised to provide that the prescribed period in which a party must act following the issuance of a document commences upon the service of that document rather than its receipt. In order to ensure that parties will have the full time prescribed in which to act, § 28.4(b) has been revised to state that a party shall have five additional days in which to act when a document is served upon that party by mail. There are a few exceptions to the rule that time periods commence upon service of a document. Actual receipt is retained as the triggering event where it is required by statute, or for a few filing requirements that are jurisdictional in nature. See, §§ 28.2(c), 28.90, 28.98(b), 28.100. A new time limit has been added requiring that motions for subpoenas be submitted to the administrative judge at least 15 days prior to the date that the hearing is scheduled to begin (§ 28.46(b)). During the discovery process, the motion for a subpoena must be submitted at least 15 days prior to the date set for the attendance of the witness at a deposition or the production of documents.

The Board has made a substantial modification in the procedures for filing charges of discrimination. The Board has retained the general rule that, in most instances, individuals who wish to allege discrimination must first file a complaint of discrimination with GAO. The individual may then file a charge with the Board's General Counsel either after the GAO issues a decision on the discrimination complaint or after at least 120 days have elapsed without a decision. However, the Board has added a new provision applicable only to individuals who have been affected by certain enumerated adverse and performance-based actions and who wish to allege that these actions were due, in whole or part, to discrimination. Individuals in these circumstances now have a choice of either filing a charge directly with the Board's General Counsel or first pursuing a discrimination complaint with GAO. See, § 28.98. Section 28.100 has also been revised to reflect that, under the Civil Rights Act of 1991, individuals now have 90 days (rather than 30 days) in which to file suit in court following notice of final agency action on their administrative complaints of discrimination.

The Board has also made several changes to the procedures applicable to labor-management relations cases. The provisions on representational elections have been revised to explain more clearly the Board's options where no labor organization on the ballot secures a majority of the votes cast (§ 28.116(d)(3)). The new regulations also provide more guidance on the filing and disposition of exceptions to an arbitrator's award (§ 28.124).

The Board has expanded the definition of a "person" to make clear that a former GAO employee may sometimes be an appropriate charging party (§ 28.3). Finally, the Board has added a new subpart which sets forth the criteria that the Board will consider in deciding whether to issue a statement of policy or guidance. See, Subpart J, § 28.155.

Summary of Comments

The Board received comments from four organizations: the General Counsel for the GAO, the Board's General Counsel, the GAO Advisory Council on Civil Rights and the GAO Advisory Council on Persons with Disabilities. The Board also received comments from two private attorneys who have practiced before the Board in the past. The comments addressed twenty-four different sections of the proposed regulations. The Board carefully considered each comment, and many suggestions contained in the comments were adopted. The more significant comments are discussed below in a section-by-section format.

Section 28.2(b) (Charges of Political Activity): Section 28.2, concerning the Board's jurisdiction, has two parts. Subsection (a) lists the actions that may be brought before the Board by the Board's General Counsel. Subsection (b) lists the actions that may be brought before the Board by "any person or groups of persons." The Board's proposal had suggested listing cases involving prohibited political activity under both subsections, rather than only under subsection (a), cases which may be brought by the Board's General Counsel. Two commentators objected to this change, while one supported it.

After carefully considering the arguments advanced in the comments, the Board decided to delete the proposed change and retain the original language of this section. While there is nothing in the General Accounting Office Personnel Act which expressly states that individuals may not bring such cases before the Board, Congress intended that the Board and its General Counsel have comparable powers to those exercised by the MSPB and the Special Counsel in the executive branch. Allegations that executive branch employees have engaged in prohibited political activity may only be brought before the MSPB by the Special Counsel. *Sims* v. *District of Columbia*, 7 M.S.P.R. 45 (1981). The Board concluded that the intent of Congress would best be effectuated if the Board followed a similar rule. Any individual who has information concerning prohibited political activity within GAO may, of course, bring this information to the attention of the Board's General Counsel. The General Accounting Office Personnel Act mandates that the General Counsel conduct an investigation of all such allegations. 31 U.S.C. 752(b)(3).

Section 28.4 (Time Limits): As noted above, changes were made throughout the regulations so that the time period in which to respond to a document generally begins to run from the date of service of the document rather than from actual receipt. Parties are given an additional five days to respond when they are served by mail. (See discussion under "Highlights" for exceptions to this rule.) Two commentators objected to this change, arguing that it sometimes takes more than five days to receive documents served by mail.

The final regulations include this proposal without modification. The Board concluded that using service as the starting point for time computations will allow both the Board and the litigants to determine with certainty the date upon which a particular action must be taken. An "actual receipt" standard does not allow for such certainty as neither the Board nor the other parties will know at the outset when a document served by mail is actually received. The Board concluded that, ordinarily, the addition of five days when a document is served by mail will be ample to ensure that parties so served are not disadvantaged. If, in rare instances, a party does not actually receive the document within five days and is thereby significantly hindered in his or her ability to make a timely response, the party can always move for an extension of time.

One commentator was concerned with the power of the administrative judge to shorten time limits for good cause shown. The commentator felt that this might particularly disadvantage some individuals with disabilities who would have difficulty responding in a shorter period of time. The Board appreciates that this is an important concern. While the Board concluded that it is desirable for its judges to retain this traditional and important power to shorten time limits in appropriate circumstances, the Board notes that any litigant may seek a modification of an order issued by a judge if the litigant believes that the order will work a hardship in the particular case.

Section 28.11(b)(4) (Continuing Violations): A majority of the Board members had suggested deleting the provision in former § 28.11(b)(5) which had stated: "Charges relating to continuing violations shall be filed at any time." They reasoned that this provision was confusing and did not fully reflect the complexity of the continuing violation theory. One Board member favored retaining the provision on the grounds that its deletion would lead some employees to conclude that their charges were time-barred when, in fact, they could be filed under the continuing violation theory.

One commentator objected to the deletion of this provision and agreed with the rationale of the dissenting Board member. Another commentator suggested that the Board add a definition of a continuing violation.

The Board decided to retain the provision on continuing violations but to change the word "shall" to "may." (The provision now appears in § 28.11(b)(4)). The Board's original proposal had been intended to eliminate confusion from the regulations. In light of the comments received and following a thorough review of this issue, the Board was persuaded that deletion of this provision would instead cause more confusion. The Board also decided that the continuing violation theory did not lend itself to a simple definition in a regulation. Rather, in applying this provision, the Board will be guided by relevant case law.

Section 28.18 (Availability of Hearing): The Board proposed deleting former § 28.18(f) which had been entitled "Right to a Hearing" and which gave employees the choice of requesting a hearing on their claims or requesting a determination based on a written record. The explanatory statement that accompanied the proposed regulations explained that the Board's policy is to hold a hearing in all cases in which there are material facts in dispute.

Three commentators objected to this change in the regulations, arguing that employees may prefer a decision based on written submissions because it may be less costly or burdensome than participating in a hearing. While the Board appreciates the concerns raised, the Board concluded that its primary responsibility is to ensure the integrity of its decisionmaking process. The Board concluded that, where there are disputes between the parties as to material facts, these issues cannot be resolved in a reliable manner without holding a hearing. The Board therefore decided not to alter its proposal. Parties are reminded, however, that they are always free to move for summary judgment (and thus avoid a hearing) where they believe that there are not material factual issues in dispute. Similarly, parties may reduce the scope (and thus the burden) of a hearing in appropriate cases by entering into stipulations as to some of the facts.

Section 28.42(d)(5) (Time Limit for Discovery): This section is unchanged from the prior regulations. It states that discovery "shall be completed by the time designated by the administrative judge, but no later than 65 days after the filing of the appeal." The rule permits the administrative judge to set a later date for the completion of discovery

after due consideration of the particular situation.

One commentator requested that the Board delete the 65 day limit and instead have the administrative judge set a time limit in each case. The Board declined to do this. The Board believes that retaining the current 65 day limit serves to put the parties on notice that expedition is necessary. If, despite due diligence, the parties cannot complete discovery in that time frame, then the rule leaves ample room for the discovery period to be extended.

Section 28.46(b) (Time Limit for Motion for Subpoena): The Board's proposed regulations included a new requirement that motions for subpoenas be submitted to the administrative judge at least 15 days before the date scheduled for the commencement of the hearing. One commentator suggested that this 15 day time limit be applied to requests for subpoenas during the discovery process as well. The Board agreed. The final version of the regulations reflects this change.

Section 28.56(g) (Witness Lists): One commentator objected to the new requirement in this section that each party, at the commencement of the hearing, submit to the administrative judge, to the court reporter and to the opposing counsel a typed list of witnesses expected to be called to testify.

While this requirement is new to the regulations, it is a common practice in Board proceedings. Most of the administrative judges require that witness lists be exchanged substantially before the hearing. This practice facilitates an orderly hearing and avoids surprise to either party. The new rule was only intended to ensure that all parties will come to the hearing with complete lists that will assist the court reporter in preparing the record. To make clear that parties frequently will be required to submit witness lists in advance of the hearing, the final rule has been revised to state that these lists must be furnished "no later than the commencement of the hearing."

Section 28.87 (Initial Decisions): This section on initial decisions by Board members had been substantially revised in the proposed regulations. One purpose of the revision was to provide parties with an opportunity to seek reconsideration from the Board member issuing a decision, prior to requesting review by the full Board. The revisions were also intended to provide detailed procedures for seeking review by the full Board.

The comments revealed that there was some ambiguity in the provisions of this section. The final rule incorporates additional revisions designed to clarify the intent of the section. Section 28.87(f) concerning remands now makes clear that the full Board has two options when it remands a case to the Board member who originally decided the matter. The Board may remand the matter without retaining jurisdiction, in which case the single Board member will issue a new initial decision which will then be subject to review in the same manner as any other initial decision. Alternatively, the Board can retain jurisdiction upon remand, in which case the single member will render a report to the full Board and the full Board will issue a final decision which will be subject only to judicial review.

Section 28.87(g), which lists the factors that the Board will consider in reviewing an initial decision, has also been revised. The list of factors has been rewritten to provide greater conformity with the factors listed in § 28.86(d) concerning Board review of recommended decisions issued by administrative judges who are not Board members. There is, however, one difference between the lists of factors in the two sections. Section 28.86(d) requires the Board to consider whether the "recommended decision is unsupported by evidence required by the requisite burden of proof as set forth at § 28.61." The Board chose not to include this factor in § 28.87(g) on review of initial decisions. The factor is appropriate in reviewing recommended decisions because the Board is required to review the record as though it were making the factual findings itself. See, § 28.86(c). The Board's review of initial decisions, however, is subject to a different standard. Although the Board may choose to review the record in such cases de novo, the Board generally defers to the factual findings contained in the initial decision unless unsupported by substantial evidence. See, § 28.87(g). Thus, the Board would generally grant such deference to a finding by the administrative judge or panel that a party had met its burden of proof. Of course, if the initial decision assigns an incorrect burden of proof, that is an error of law that is subject to Board review under § 28.87(g) (2) and (3).

Section 28.95 (Rehabilitation Act): The GAO objected to the references to the Rehabilitation Act that appear in this and other sections of the regulations. The GAO asserted, without providing legal argument, that the Rehabilitation Act does not apply to GAO employees. From the time that the Board's regulations were first promulgated in 1981, they have contained references to the Rehabilitation Act. See, 46 FR 15857, 15862 (March 10, 1981). These references were patterned after the General Accounting Office Personnel Act which specifically mentioned the Rehabilitation Act. Pub. L. 96–191, section 3(g)(3), 94 Stat. 27, 28 (1980). The Board does not think that it would be appropriate to eliminate these references (and implicitly to eliminate protection for GAO employees under the Rehabilitation Act) as part of a rulemaking procedure where there has not been a full, adversarial presentation of the issue of the applicability of that statute to GAO employees. The Board will address this issue if and when it is properly presented to the Board in an adjudicatory setting.

Section 28.98(b) (Time Limits for Filing Charges of Discrimination): The final regulation retains the provisions of the prior rule permitting a GAO employee to file a charge of discrimination with the Board's General Counsel if 120 days have elapsed since the employee filed a discrimination complaint with GAO and GAO has not issued a final decision. GAO suggested that this period be enlarged to 180 days to be consistent with EEOC practice.

While it is true that EEOC regulations give agencies 180 days to resolve complaints of discrimination (29 CFR 1614.108(e)), the Board's jurisdiction includes both matters that would be heard by EEOC and those that would be heard by MSPB. MSPB regulations only give agencies 120 days to resolve "mixed cases" which involve both allegations of discrimination and personnel actions that would otherwise be appealable to the MSPB. 5 CFR 1201.154(b)(2). That 120 day limit is mandated by statute. 5 U.S.C. 7702(a)(2). Because the Board's jurisdiction includes both mixed cases and "pure" discrimination cases, the Board concluded that it was most appropriate to retain the shorter 120 day period as the single time limit applicable to both kinds of cases. The Board notes that GAO did not argue that it is having any practical difficulty in resolving cases within this time frame.

Section 28.98(c) (New Choice of Procedures for Adverse or Performance-based Actions Alleged to be Due to Discrimination): This new subsection gives GAO employees affected by serious adverse or performance-based actions, who wish to allege that discrimination was a factor in those actions, a choice of either coming directly to the Board's General Counsel or first pursuing the matter through the GAO EEO process.

This new subsection represents a substantial change from the prior regulations. Those regulations had required every individual who wished to include allegations of discrimination in a charge first to file a complaint of discrimination with GAO. The individual could not file a charge with the Board's General Counsel until either the GAO issued a decision on the EEO complaint or at least 120 days had elapsed without a decision. This applied even where a GAO employee had been affected by a serious adverse or performance-based action which would otherwise be appealable directly to the Board. This was in sharp contrast to the procedures applicable to other federal employees. Executive branch employees who wish to allege that a personnel action, otherwise appealable to the MSPB, was due in whole or part to discrimination have the choice of either filing directly with the MSPB or pursuing the discrimination complaint process within their agency. 29 CFR 1614.302; 5 CFR 1201.154. The Board concluded that GAO employees were disadvantaged by this different procedure because they could not seek immediate impartial review outside their agency for serious personnel actions affecting them and because the required 120 day delay could cause substantial hardship in many cases.

Two commentators praised this change and none objected to it. The GAO, however, did request that employees opting to come first to the Board still be permitted to participate in confidential mediation through GAO's Civil Rights Office, and that the Board's General Counsel stay its investigation of the matter pending the outcome of the mediation process. The Board has decided not to adopt this suggestion. The whole purpose of the new provision is to give GAO employees who have been terminated, suspended or reduced in grade the opportunity to obtain an early review of that decision by an impartial body. Staying the Board's proceedings would undermine this intent.

The rule puts the choice in the hands of the employee. Any employee who feels that mediation or any other service offered by the Civil Rights Office would be in his or her interest may simply elect to file first with that office. Because the regulation expressly permits an employee to consult with an EEO counselor without that constituting an election of the GAO process, the employee is given ample opportunity to learn of the services offered by the Civil Rights Office and make an informed choice of forum. Of course, GAO may still choose to offer mediation to an employee who opts to file first with the Board. But the Board does not believe that an automatic stay of its proceedings under such circumstances would be warranted.

Section 28.100 (Availability of Trial De Novo Following Board Decision): Section 28.100(a)(2) states that a GAO employee may file suit in federal district court following the receipt of a final decision by the Board. In its comments, GAO notes that this is inconsistent with the position taken by the Justice Department, as counsel for GAO, in *Ramey* v. *Bowsher*, Appeal No. 92–5096, which is currently pending before the United States Court of Appeals for the District of Columbia Circuit. In that case, the Justice Department is arguing that, following receipt of a Board decision, an employee's only option is to seek appellate review before the United States Court of Appeals for the Federal Circuit, pursuant to 31 U.S.C. 755. By contrast, other federal employees covered by Title VII have the right to a trial de novo in federal district court following the receipt of a final decision by the EEOC or the MSPB concerning a discrimination appeal.

Because the *Ramey* case has not yet been decided by the District of Columbia Circuit, it would be premature to make any change in the Board's regulations at this time. The Board will review this issue once there has been a final disposition of the *Ramey* case.

Section 28.133 (Stay Proceedings): In the proposed regulations, this section on requests for stays of personnel actions was substantially revised to provide more detailed procedures for such requests. GAO raised several concerns about this section.

GAO's first concern was that the section did not specifically state that GAO would be served with a copy of the request for an ex parte stay. While the Board felt that the regulations did require service of this and any other pleading or motion in a Board proceeding, the section has been revised to state this expressly so as to eliminate any ambiguity on this point.

GAO also offered the opinion that the description of the contents of the request for an ex parte stay and the standard to be applied by the Board in deciding whether to issue the ex parte stay were too lax and vague. The Board has carefully reviewed this section and determined that it provides sufficient guidance. The Board notes that the standards in subsection (a) only relate to ex parte stays issued for not more than 30 days. In order to obtain a longer temporary stay or a permanent stay, the General Counsel would have to meet the more stringent requirements set forth in subsections (b) through (e).

Finally, GAO objects to the provision in subsection (d) which permits the Board sua sponte to extend the ex parte stay for a period not to exceed 30 days if this is necessary to give the Board a reasonable opportunity to decide whether to grant a request for an additional temporary or permanent stay. GAO argues that this places its personnel actions "in limbo" for an unacceptable period of time. The Board has reviewed the time frames in this section and determined that they are reasonable. The Board notes that the revisions to § 28.133, in general, represent a shortening of the time frames for stays. Under the prior regulations, the General Counsel could obtain an initial stay of 60 days. Now the time period for an ex parte stay has been shortened to 30 days. The General Counsel can only obtain a longer stay by prevailing in an adversarial proceeding. Permitting the Board itself to extend the ex parte stay for a brief period necessary to allow adjudication of a further stay request is reasonable and not unduly burdensome.

Section 28.141 (Informal Hearings for SES Members in Performance-based Actions): Career appointees in the Senior Executive Service (SES) who are removed to positions outside the SES for less than fully successful executive performance are entitled to an informal hearing before a member of the Board. This section has been revised to provide more details about the nature of that informal hearing.

GAO requested that certain language which had appeared in the prior version of the rule and which emphasized the limited nature of the rights of the removed SES member should be reinstated in the rule. The Board concluded that, since this language had been based on statutory requirements, it would be helpful to include the language in the final regulation so as not to mislead any employee about the extent of their rights in this situation. The final regulation thus includes a statement that the granting of an informal hearing does not give the career appointee the right to initiate an appeal with the Board under any other section of the regulations nor require the delaying of the removal action.

Subpart J, § 28.155 (Statements of Policy or Guidance): This is a new subpart which sets forth the criteria that the Board will consider in deciding whether to issue a statement of policy or guidance. The criteria were adapted from the Board's decision in *GS–13/14 Management and Policy Advisory*

Council v. *GAO*, Docket No. 116–600–GC–89 (Sept. 20, 1991).

GAO objects to this section, arguing that the Board lacks authority to issue statements of policy or guidance except in the area of labor-management relations where the Comptroller General delegated such authority to the Board. The Board, however, rejected this argument in the *GS–13/14* case and held that its authority to issue policy statements on labor-management relations was not dependent upon a delegation from the Comptroller General. The Board has reviewed its authority in other areas and concluded that it is also sufficiently broad to support the issuance of policy statements in appropriate cases.

List of Subjects

4 CFR Part 27

Government employees, Organization and functions (government agencies).

4 CFR Part 28

Administrative practice and procedure, Equal employment opportunity, Government employees, Labor-management relations.

For the reasons set out in the preamble, 4 CFR Ch.I is amended as follows:

1. Part 27 is revised to read as follows:

PART 27—GENERAL ACCOUNTING OFFICE PERSONNEL APPEALS BOARD; ORGANIZATION

Sec.
27.1 The Board.
27.2 The Chair, Vice Chair.
27.3 The General Counsel.

Authority: 31 U.S.C. 753.

§ 27.1 The Board.

The General Accounting Office Personnel Appeals Board, hereinafter the Board, is composed of five members appointed by the Comptroller General, in accordance with the provisions of 31 U.S.C. 751. The Board may designate a panel of its members or an individual Board member to take any action within the scope of the Board's authority, subject to later reconsideration by the Board.

§ 27.2 The Chair, Vice Chair.

The members of the Board shall select from among its membership a Chairperson, hereinafter the Chair, who shall serve as the chief executive and administrative officer of the Board. The Members of the Board may select from among its membership a Vice Chairperson, hereinafter the Vice Chair, who shall serve in the absence of the Chair and in other matters delegated by the Chair.

§ 27.3 The General Counsel.

The Chair shall select an individual and the Comptroller General shall appoint the individual selected by the Chair to serve as the General Counsel of the Board. The General Counsel, at the request of the Board, shall investigate matters under the jurisdiction of the Board, and otherwise assist the Board in carrying out its functions, unless to do so would create a conflict of interest for the General Counsel.

2. Part 28 is revised to read as follows:

PART 28—GENERAL ACCOUNTING OFFICE PERSONNEL APPEALS BOARD; PROCEDURES

Subpart A—Purpose, General Definitions, and Jurisdiction

Sec.
28.1 Purpose and scope.
28.2 Jurisdiction.
28.3 General definitions.
28.4 Computation of time.

Subpart B—Procedures

28.8 Informal procedural advice.
28.9 Procedures; general.
28.10 Notice of appeal rights.
28.11 Filing a charge with the General Counsel.
28.12 General Counsel procedures.

Hearing Procedures for Cases Before the Board—General

28.15 Scope and policy.
28.16 Revocation, amendment or waiver of rules.
28.17 Internal appeals of Board employees.
28.18 Filing a petition for review with the Board.
28.19 Content of response by charged party.
28.20 Number of pleadings, service and response.
28.21 Prehearing procedures and motions practice.
28.22 Administrative judges.
28.23 Disqualification of administrative judges.
28.24 Sanctions.

Parties, Practitioners and Witnesses

28.25 Representation.
28.26 Witness fees.
28.27 Intervenors.
28.28 Substitution.
28.29 Consolidation or joinder.

Discovery

28.40 Statement of purpose.
28.41 Explanation, scope and methods.
28.42 Discovery procedures and protective orders.
28.43 Compelling discovery.
28.44 Taking of depositions.
28.45 Admissions of facts and genuineness of documents.

Subpoenas

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Hearings

28.55 Scheduling the hearing.
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28.57 Public hearings.
28.58 Transcript.
28.59 Official record.
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28.61 Burden and degree of proof.
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Evidence

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Board Decisions, Attorney's Fees and Judicial Review

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28.91 General.
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28.95 Purpose and scope.
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28.100 Civil action; discrimination complaints.
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Subpart E—Special Procedures; Representation Proceedings

28.110 Purpose.
28.111 Scope.
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28.113 Contents of representation petitions.
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Subpart F—Special Procedures; Unfair Labor Practices

28.120 Authority of the Board.
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Subpart G—Corrective Action, Disciplinary and Stay Proceedings

28.130 General authority.
28.131 Corrective action proceedings.
28.132 Disciplinary proceedings.
28.133 Stay proceedings.

Subpart H—Appeals by Members of the Senior Executive Service

28.140 Personnel actions involving SES members.
28.141 Performance based actions.

Subpart I—Ex Parte Communications

28.145 Policy.
28.146 Explanation and definitions.
28.147 Prohibited communications.
28.148 Reporting of communications.
28.149 Sanctions.

Subpart J—Statements of Policy or Guidance

28.155 Statements of policy or guidance.

Authority: 31 U.S.C. 753.

Subpart A—Purpose, General Definitions, and Jurisdiction

§28.1 Purpose and scope.

(a) The purpose of these rules is to establish the procedures to be followed:

(1) By the GAO, in its dealings with the Board;

(2) By employees of the GAO or applicants for employment by the GAO, or by groups or organizations claiming to be affected adversely by the operations of the GAO personnel system;

(3) By employees or organizations petitioning for protection of rights or extension of benefits granted to them under Subchapters III and IV of Chapter 7 of Title 31, U.S.C.; and

(4) By the Board, in carrying out its responsibilities under Subchapters III and IV of Chapter 7 of Title 31, U.S.C.

(b) The scope of the Board's operations encompasses the investigation and, where necessary, adjudication of cases arising under 31 U.S.C. 753. In addition, the Board has authority for oversight of the equal employment opportunity program at GAO. This includes the review of policies and evaluation of operations as they relate to EEO objectives and, where necessary, the ordering of corrective action for violation of or inconsistencies with equal employment opportunity laws.

(c) In considering any procedural matter not specifically addressed in these rules, the Board will be guided, but not bound, by the Federal Rules of Civil Procedure.

§28.2 Jurisdiction.

(a) The Board has jurisdiction to hear and decide the following actions brought by the General Counsel:

(1) Proceedings in which the General Counsel seeks to stay a personnel action based upon an alleged prohibited personnel practice that has occurred or is about to occur;

(2) Proceedings in which the General Counsel seeks corrective action for an alleged prohibited personnel practice; and

(3) Proceedings in which the General Counsel seeks discipline for a GAO employee who has allegedly committed a prohibited personnel practice or who has engaged in prohibited political activity.

(b) The Board has jurisdiction to hear any action brought by any person or group of persons in the following subject areas:

(1) An officer or employee appeal involving a removal, suspension for more than 14 days, reduction in grade or pay, or furlough of not more than 30 days;

(2) A prohibited personnel practice under 31 U.S.C. 732(b)(2);

(3) A decision of an appropriate unit of employees for collective bargaining;

(4) An election or certification of a collective bargaining representative;

(5) A matter appealable to the Board under the labor-management relations program under 31 U.S.C. 732(e), including an unfair labor practice under 31 U.S.C. 732(e)(1);

(6) An action involving discrimination prohibited under 31 U.S.C. 732(f)(1); and

(7) An issue about GAO personnel which the Comptroller General by regulation decides the Board shall resolve.

(c) *Special jurisdictional rules where matters are covered by a negotiated grievance procedure.* If a GAO employee is covered by a collective bargaining agreement containing a negotiated grievance procedure that permits the employee to grieve matters that would otherwise be appealable to the Board, the following special rules apply:

(1) Matters involving discrimination, performance-based reduction in grade or removal, or adverse action. If the negotiated grievance procedure permits the employee to grieve matters involving prohibited discrimination (as defined in § 28.95), performance-based reduction in grade or removal (as described in 5 U.S.C. 4303) or an adverse action (as described in 5 U.S.C. 7512), then the employee may elect to raise the matter either under the negotiated grievance procedure or under the Board's procedures, but not both. The employee will be deemed to have elected the Board's procedures if the employee files a timely charge with the Board's General Counsel or files a timely written EEO complaint with GAO before filing a timely written grievance.

(2) Other matters. If the negotiated grievance procedure permits the employee to grieve any matters which would otherwise be appealable to the Board, other than those listed in paragraph (c)(1) of this section, then those matters may only be raised under the negotiated grievance procedure and not before the Board.

(3) Board review of final decisions from the negotiated grievance procedure involving discrimination. If an employee elects to pursue a matter involving prohibited discrimination (as defined in § 28.95) through the negotiated grievance procedure, the employee may ask the Board to review the final decision of the negotiated grievance procedure as it relates to the issue of discrimination. A petition seeking such review shall be filed with the Clerk of the Board within 20 days of receipt of the final decision of the negotiated grievance procedure. The Board will not review any final decisions of the negotiated grievance procedure other than those where prohibited discrimination was raised as an issue in the grievance.

§28.3 General definitions.

In this part—

Administrative judge means any individual designated by the Board to preside over a hearing conducted on matters within its jurisdiction. An administrative judge may be a member of the Board, an employee of the Board, or any individual qualified by experience or training to conduct a hearing who is appointed to do so by the Board. When a panel of members or the full Board is hearing a case, the Chair shall designate one of the members to exercise the responsibilities of the administrative judge in the proceedings.

Board means the General Accounting Office Personnel Appeals Board as established by 31 U.S.C. 751.

Charge means any request filed with the PAB General Counsel on any matters within the jurisdiction of the Board, under the provisions of Subchapter IV of Chapter 7 of Title 31, United States Code.

Charging Party means any person filing a charge with the General Counsel for investigation.

Comptroller General means the Comptroller General of the United States.

Days means calendar days.

Exceptions to the Recommended Decision means a request filed by a party with the Board that objects to the findings and/or conclusions of a recommended decision.

GAO means the General Accounting Office.

General Counsel means the General Counsel of the Board, as provided for under 31 U.S.C. 752.

Initial Decision means the adjudicatory statement of a case that is issued by an administrative judge who is a member of the Board.

Person means an employee, an applicant for employment, a former employee, a labor organization or the GAO.

Petition for Review means any request filed with the Board for action to be taken on matters within the jurisdiction of the Board, under the provisions of Subchapter IV of Chapter 7 of Title 31, United States Code.

Petitioner means any person filing a petition for review for Board consideration.

Pleading means a document that initiates a cause of action before the Board, responds to a cause of action, amends a cause of action, responds to an amended cause of action, requests reconsideration of a decision, responds to a request for reconsideration of a recommended decision or responds to such a request.

Recommended Decision means the adjudicatory statement of a case that is issued by an administrative judge who is not a member of the Board at the time of the decision.

Request for Reconsideration means a request, filed with the administrative judge who rendered the initial decision, to reconsider that decision in whole or part.

Request for Review means a request filed with the full Board for review of an initial decision.

Solicitor means the attorney appointed by the Board to provide advice and assistance to the Board in carrying out its adjudicatory functions and to otherwise provide assistance as directed by the Board.

§ 28.4 Computation of time.

(a) To compute the number of days for filing under these rules, the first day shall be the day after the event from which the time period begins to run and the last day for filing shall be included in the computation. When the last day falls on a Saturday, Sunday or federal government holiday, then the filing deadline will be the next regular federal government workday.

(b) Whenever a party has the right or is required to do some act within a prescribed period after the service of a notice or other paper upon him or her and the notice or paper is served by mail, five (5) days shall be added to the prescribed period. Only two (2) days shall be added when a document is served by express mail or other form of expedited delivery.

(c) Except as otherwise provided by law, whenever an act is required or allowed to be done at or within a specified period of time, the time fixed or the period of time prescribed may for good cause be extended or shortened by the Board or administrative judge.

Subpart B—Procedures

§ 28.8 Informal procedural advice.

(a) Persons may seek informal advice on all aspects of the Board's procedures by contacting the Board's Solicitor, the Board's General Counsel or the Clerk of the Board.

(b) Informal procedural advice will be supplied within the limits of available time and staff.

§ 28.9 Procedures; general.

(a) The procedures described in this subpart are generally applicable to the processing of all matters presented for consideration by the Board. Where special procedures are to be followed, they will be prescribed in those subsequent subparts to which they are particularly applicable.

(b) No pleading, motion or supporting memorandum filed with the Board shall exceed 60 pages, exclusive of attachments. The Board or the administrative judge may waive this limitation for good cause shown. Pleadings, motions and supporting memoranda, and attachments thereto, shall be on standard letter-size paper (8½x11).

§ 28.10 Notice of appeal rights.

(a) The GAO shall be responsible for ensuring that employees are routinely advised of their appeal rights to the Board and that employees who are the object of an adverse or performance-based action are, at the time of the action, adequately advised of their appeal rights to the Board. The notice in adverse or performance-based actions must be accompanied by proof of service.

(b) The notice in adverse or performance-based actions shall include:

(1) Time limits for appealing to the Board and the address of the Board;

(2) A copy of the Board's regulations; and

(3) Notice of the right to representation, and the availability of a hearing before the Board where factual issues are in dispute.

§ 28.11 Filing a charge with the General Counsel.

(a) *Who may file.* (1) Any person claiming to be affected adversely by GAO action or inaction which is within the Board's jurisdiction under Subchapter IV of Chapter 7 of Title 31, United States Code, may file a charge with the General Counsel.

(2) Non-EEO class actions. One or more persons may file a charge as representative of a class in any matter within the Board's jurisdiction. See § 28.97 for EEO class actions.

(3) Unfair labor practice proceedings. Any person may file a charge alleging that the GAO or a labor organization has engaged or is engaging in an unfair labor practice. (The types of allegations which may be included in an unfair labor practice charge are discussed at § 28.121(a)).

(b) *When to file.* (1) Charges relating to adverse and performance-based actions must be filed within 20 days after the effective date of the action.

(2) Charges relating to other personnel actions must be filed within 20 days after the effective date of the action or 20 days after the charging party knew or should have known of the action.

(3) Charges which include an allegation of prohibited discrimination shall be filed in accordance with the special rules set forth in § 28.98.

(4) Charges relating to continuing violations may be filed at any time.

(c) *How to file.* Charges may be filed with the General Counsel in person or by mail. Please note that the address to be used differs for the two kinds of filing.

(1) *Filing in person:* A charge may be filed in person at the Office of the General Counsel, Suite 840, Union Center Plaza II, 820 First Street, NE., Washington, DC.

(2) *Filing by mail:* A charge may be filed by mail addressed to the General Counsel, Personnel Appeals Board, Suite 840, Union Center Plaza II, 441 G Street, NW., Washington, DC 20548. When filed by mail, the postmark shall be the date of filing for all submissions to the General Counsel.

(d) *What to file.* The charging party should include in any charge the following information:

(1) Name of the charging party or a clear description of the group or class of persons on whose behalf the charge is being filed;

(2) The names and titles of persons, if any, responsible for actions the charging party wishes to have the General Counsel review;

(3) The actions complained about, including dates, reasons given, and internal appeals taken;

(4) The charging party's reasons for believing the actions to be improper;

(5) Remedies sought by the charging party;

(6) Name and address of the representative, if any, who will act for the charging party in any further stages of the matter; and

(7) Signature of the charging party or the charging party's representative.

(e) The General Counsel shall not represent a petitioner when the only issue is attorney fees. When attorney fees are the only issue raised in a charge to the General Counsel, the General Counsel shall transmit the charge to the Board for processing under §§ 28.18 through 28.88 as a petition for review.

§ 28.12 General Counsel procedures.

(a) The General Counsel shall serve on the GAO or other charged party a copy of the charge, investigate the matters raised in a charge, refine the issues where appropriate, and attempt to settle all matters at issue.

(b) The General Counsel's investigation may include gathering information from the GAO or other charged party, and interviewing and taking statements from witnesses. Employees of GAO who are requested by the General Counsel to participate in any investigation under these Rules shall be on official time.

(c) Following the investigation, the General Counsel shall provide the charging party with a Right to Appeal Letter. Accompanying this letter will be a statement of the General Counsel advising the charging party of the results of the investigation. This statement of the General Counsel is not subject to discovery and may not be introduced into evidence before the Board.

(d) If, following the investigation, the General Counsel determines that there are not reasonable grounds to believe that the charging party's rights under Subchapters III and IV of Chapter 7 of Title 31, United States Code, have been violated, then the General Counsel shall not represent the charging party. If the General Counsel determines that there are reasonable grounds to believe that the charging party's rights under Subchapters III and IV of Chapter 7 of Title 31, United States Code, have been violated, then the General Counsel shall represent the charging party, unless the charging party elects not to be represented by the General Counsel. Any charging party may represent him or herself or obtain other representation.

(e) When the charging party elects to be represented by the General Counsel, the General Counsel is to direct the representation in the charging party's case. The charging party may also retain a private representative in such cases. However, the role of a private representative is limited to assisting the General Counsel as the General Counsel determines to be appropriate.

(f) When the General Counsel is not participating in a case, the General Counsel may request permission to intervene with regard to any issue in which the General Counsel finds a significant public interest with respect to the preservation of the merit system.

Hearing Procedures for Cases Before the Board—General

§ 28.15 Scope and policy.

The rules in this subpart apply to actions brought by any person, except as otherwise provided in § 28.17 (concerning internal appeals of Board employees). These rules also apply to actions brought by the General Counsel, except as otherwise provided in subpart G (concerning corrective action, disciplinary and stay proceedings). It is the policy of the Board that these rules shall be applied in a manner which expedites the processing of each case, but with due regard to the rights of all parties.

§ 28.16 Revocation, amendment or waiver of rules.

(a) The Board may revoke or amend these regulations by publishing proposed changes within GAO and providing for a comment period of not less than 30 days. Following the comment period, any changes to the rules are final once they are published in the **Federal Register**. Notice of publication in the **Federal Register** must be published throughout GAO.

(b) An administrative judge or the Board may waive a Board regulation in an individual case for good cause shown if application of the regulation is not required by statute.

§ 28.17 Internal appeals of Board employees.

(a) The provisions of the GAO Personnel Act, its implementing regulations, and the Board's procedural rules apply in the same manner to employees of the Board as they do to other GAO employees, with the following exceptions.

(1) The General Counsel serves at the pleasure of the Chair. The General Counsel may not bring any complaint or charge concerning his or her own employment except to allege that he or she has been the victim of prohibited discrimination or a prohibited personnel practice as defined in 31 U.S.C. 732 (b)(2) or (f)(1).

(2) When an employee of the Board believes that he or she has been denied his or her right to equal employment opportunity, the employee shall consult either with the Solicitor or with the General Counsel and seek advice on filing an EEO complaint. If the matter cannot be resolved within 10 days, the Solicitor or General Counsel shall notify the employee of his or her right to file an EEO complaint. The employee shall have 20 days from service of this notice to file an EEO complaint with the General Counsel. Upon receipt of an EEO complaint, the General Counsel shall arrange for processing in accordance with paragraph (b) of this section.

(3) When an employee of the Board wishes to raise any other issue that would be subject to the Board's jurisdiction, the employee shall file a charge with the General Counsel and the General Counsel shall arrange for processing in accordance with paragraph (b) of this section.

(b) The responsibilities and functions of the Board's General Counsel will be assumed by an attorney who is not a current or former employee of the Board or the GAO. The services of that attorney, who shall be knowledgeable in federal personnel matters, will be paid for by the Board. The attorney will be selected by an impartial body as described below.

(1) If agreed to by the Special Counsel of the Merit Systems Protection Board (MSPB) (or the EEOC, as appropriate), that body will appoint and detail a person from among its attorneys to perform the functions of the General Counsel.

(2) If the MSPB Special Counsel (or the EEOC) does not agree to such a procedure, an appointment of an attorney will be sought from the Federal Mediation and Conciliation Service (FMCS).

(3) In any event, whoever is so appointed shall possess all of the powers and authority possessed by the General Counsel in employee appeal cases.

(c) The adjudication responsibilities and functions of the Board will be assumed by a person who is not a current or former employee of the Board or the GAO. The services of that person, who shall be knowledgeable in federal personnel matters, will be paid for by the Board. The person will be selected by an impartial body as described below.

(1) If agreed to by the MSPB (or the EEOC, as appropriate), that body will appoint and detail one of its administrative law judges (ALJ) or administrative judges (AJ) to perform the Board's adjudicative functions.

(2) If the MSPB (or the EEOC) does not agree to such a procedure, an appointment of an arbitrator will be sought from the FMCS.

(3) In any event, whoever is so appointed shall possess all of the powers and authority possessed by the Board in employee appeals cases. The

decision of the administrative law judge, administrative judge or arbitrator shall be a final decision of the Board, in the same manner as if rendered by the Board under § 28.86(e). The procedure for judicial review of the decision shall be the same as that described in § 28.90 or § 28.100, as appropriate.

(d) Any employee of the Board (other than the General Counsel) who believes that he or she is aggrieved by any personnel matter that is not reviewable by the Board under 31 U.S.C. 753(a) may file a grievance as follows:

(1) *Informal Step.* The employee must discuss the complained of incident with his or her supervisor as soon as possible after the complained of incident.

(2) *Step 1.* If the supervisor is unable to resolve the matter informally to the satisfaction of the employee, then the employee may file a formal grievance with the supervisor. The formal grievance must be filed by the employee with the supervisor within 20 days after the complained of incident. The supervisor must respond to the employee in writing within 10 days.

(3) *Step 2.* (i) If the employee is not satisfied with the supervisor's response, the employee has 10 days in which to appeal to the Chair. In this appeal, the employee must forward to the Chair the formal grievance, the supervisor's response and a brief statement from the employee explaining why the supervisor's response is not satisfactory.

(ii) The Chair or another member designated by the Chair, shall meet with the employee and discuss the matter of concern within 10 days after service of the step 2 appeal. The Chair or designee shall issue a written resolution of the grievance.

(4) *Step 3.* Within 10 days after service of the Chair's resolution or within 60 days after initiating step 2, whichever occurs first, the employee may request that the full Board review the grievance. The decision of the full Board is the final decision in the matter.

§ 28.18 Filing a petition for review with the Board.

(a) *Who may file.* Any person who has received a Right to Appeal letter from the General Counsel and who is claiming to be affected adversely by GAO action or inaction which is within the Board's jurisdiction under Subchapter IV of Chapter 7 of Title 31, United States Code, may file a petition for review. A petition for review may also be filed by any person who has received a Right to Appeal letter from the General Counsel and who is alleging that the GAO or a labor organization engaged or is engaging in an unfair labor practice.

(b) *When to file.* Petitions for review must be filed within 20 days after service upon the charging party of the Right to Appeal Letter from the General Counsel.

(c) *How to file.* Petitions may be filed in person or by mail. Please note that the address to be used differs for the two kinds of filing.

(1) *Filing in person:* A petition may be filed in person at the office of the Board, Suite 830, Union Center Plaza II, 820 First Street, NE., Washington, DC.

(2) *Filing by mail:* A petition may be filed by mail addressed to the Personnel Appeals Board, suite 830, Union Center Plaza II, 441 G Street, NW., Washington, DC 20548. When filed by mail, the postmark shall be the date of filing for all submissions to the Board.

(d) *What to file.* The petition for review shall include the following information:

(1) Name of the petitioner or a clear description of the group or class of persons on whose behalf the petition is being filed;

(2) The names and titles of persons, if any, responsible for actions the petitioner wishes to have the Board review;

(3) The actions being complained about, including dates, reasons given and internal appeals taken;

(4) Petitioner's reasons for believing the actions to be improper;

(5) Remedies sought by the petitioner;

(6) Name and address of the representative, if any, who will act for the petitioner in any further stages of the matter; and

(7) Signature of the petitioner or petitioner's representative.

(e) Failure to raise a claim or defense in the petition for review shall not bar its submission later unless to do so would prejudice the rights of the other parties or unduly delay the proceedings.

(f) *Non-EEO class actions.* One or more persons may file a petition for review as representatives of a class in any matter within the Board's jurisdiction. For the purpose of determining whether it is appropriate to treat an appeal as a class action, the administrative judge will be guided, but not controlled, by the applicable provisions of the Federal Rules of Civil Procedure. See § 28.97 for EEO class actions.

§ 28.19 Content of response by charged party.

(a) Within 20 days after service of a copy of a petition for review, the GAO or other charged party shall file a response containing at least the following:

(1) A statement of the position of the charged party on each of the issues raised by the petitioner, including admissions, denials or explanations of each allegation made in the petition and any other defenses to the petition.

(2) Designation of, and signature by, the representative authorized to act for the charged party in the matter.

(b) Failure to raise a claim or defense in the response shall not bar its submission later unless to do so would prejudice the rights of the other parties or unduly delay the proceedings.

§ 28.20 Number of Pleadings, service and response.

(a) *Number.* One original and seven copies of all pleadings (see definition in § 28.3) must be filed with the Board. However, when before a single administrative judge, one original and three copies will be adequate unless informed otherwise.

(b) *Service—(1) Service by the Board.* The Board will serve copies of a petition for review upon the parties to the proceeding by mail. The Board will attach a service list indicating the names and addresses of the parties to the proceeding or their designated representatives. The Board will not serve copies of any pleadings, motions, or other submissions by the parties after the initial petition for review.

(2) *Service by the parties.* The parties shall serve on each other one copy of all pleadings other than the initial petition for review. Service shall be made by mailing or by delivering personally a copy of the pleading to each party on the service list previously provided by the Board. Each pleading must be accompanied by a certificate of service specifying how and when service was made. It shall be the duty of all parties to notify the Board and one another in writing of any changes in the names or addresses on the service list.

(c) *Time limitations for response to pleadings.* Unless otherwise specified by the administrative judge or this subpart, a party shall file a response to a pleading within 20 days of the service of that pleading upon the party.

(d) Size limitations are set forth at § 28.9(b).

§ 28.21 Prehearing procedures and motions practice.

(a) *Amendments to petitions.* The Board, at its discretion, may allow amendments to a petition for review as long as all persons who are parties to the proceeding have adequate notice to prepare for the new allegations and if to do so would not prejudice the rights of the other parties or unduly delay the proceedings.

(b) *Motions practice.* When an action is before an administrative judge,

motions of the parties shall be filed with the administrative judge and shall be in writing except for oral motions made during the hearing. An original and 3 copies of written motions shall be filed with the administrative judge. When an action is before the full Board, an original and 7 copies of any motion shall be filed with the Board. Copies shall be served simultaneously upon the other parties to the proceeding. An original and 3 copies of responses in opposition to written motions must be filed with the administrative judge, or if the action is before the full Board an original and 7 copies must be filed with the Board, and served simultaneously upon the other parties to the proceeding. Responses shall be filed within 20 days of service of the motion, unless the administrative judge requires a shorter response time. All written motions and responses thereto shall include a proposed order, where applicable. A certificate of service will be filed with all motions and responses thereto showing service by mail or personal delivery of the motion to the other parties. Additional responses to the motion or to the response to the motion by either party may be filed only with the approval of the administrative judge. Motions for extension of time will be granted only for good cause shown.

(c) *Oral argument.* The administrative judge may allow oral argument on the motion at his or her discretion.

(d) *General Counsel Settlement.* Where the General Counsel under § 28.12(a) transmits a settlement which has been agreed to by the parties, the settlement agreement shall be the final disposition of the case.

§ 28.22 Administrative judges.

(a) *Exercise of authority.* Administrative judges may exercise authority as provided in paragraph (b) of this section upon their own initiative or upon the motion of a party, as appropriate.

(b) *Authority.* Administrative judges shall conduct fair and impartial hearings and take all necessary action to avoid delay in the disposition of all proceedings. They shall have all powers necessary to that end unless otherwise limited by law, including, but not limited to, the authority to:

(1) Administer oaths and affirmations;

(2) Issue subpoenas in accordance with § 28.46;

(3) Rule upon offers of proof and receive relevant evidence;

(4) Rule upon discovery issues as appropriate under §§ 28.42 through 28.45;

(5) Convene a hearing as appropriate, regulate the course of the hearing, maintain decorum and exclude from the hearing any disruptive persons;

(6) Exclude from the hearing any witness, except the petitioner(s), whose later testimony might be colored by testimony of other witnesses, or any persons whose presence might have a chilling effect on a testifying witness;

(7) Rule on all motions, witness and exhibit lists and proposed findings;

(8) Require the filing of memoranda of law and the presentation of oral argument with respect to any question of law;

(9) Order the production of evidence and the appearance of witnesses whose testimony would be relevant, material and not repetitious;

(10) Impose sanctions as provided under § 28.24 of this part;

(11) Hold prehearing conferences for the settlement and simplification of issues; and

(12) File recommended or initial decisions, as appropriate.

§ 28.23 Disqualification of administrative judges.

(a) In the event that an administrative judge considers himself or herself disqualified, he or she shall withdraw from the case, stating on the record the reasons therefor, and shall immediately notify the Board of the withdrawal.

(b) Any party may file a motion requesting the administrative judge to withdraw on the basis of personal bias or other disqualification and specifically setting forth the reasons for the request. This motion shall be filed as soon as the party has reason to believe there is a basis for disqualification.

(c) The administrative judge shall rule on the withdrawal motion. If the motion is denied, the party requesting withdrawal may take an appeal to the full Board. The notice of appeal, together with a supporting brief, shall be filed within 15 days of service of the denial of the motion. Upon receipt of the appeal, the Board will determine whether a response from the other party or parties is required, and if so, will fix by order the time for the filing of the response.

§ 28.24 Sanctions.

The administrative judge may impose sanctions upon the parties as necessary to serve the ends of justice, including but not limited to the instances set forth in this section.

(a) *Failure to comply with an order.* When a party fails to comply with an order (including an order for the taking of a deposition, for the production of evidence within the party's control, for an admission, or for production of witnesses), the administrative judge may:

(1) Draw an inference in favor of the requesting party on the issue related to the information sought.

(2) Prohibit the party failing to comply with such order from introducing evidence concerning, or otherwise relying upon, testimony relating to the information sought.

(3) Permit the requesting party to introduce secondary evidence concerning the information sought.

(4) Strike any part of the pleadings or other submissions of the party failing to comply with such request.

(b) *Failure to prosecute or defend.* If a party fails to prosecute or defend an appeal, the administrative judge may dismiss the action with prejudice or rule for the petitioner.

(c) *Failure to make timely filing.* The administrative judge may refuse to consider any motion or other action which is not filed in a timely fashion in compliance with this subpart.

Parties, Practitioners and Witnesses

§ 28.25 Representation.

(a) All parties to an appeal may be represented in any matter relating to the appeal. The parties shall designate their representatives, if any, in the petition for review or responsive pleading. Any subsequent changes in representation shall also be in writing, and submitted to the administrative judge and served upon the other parties. Once a party has designated a representative, all documents required by the Board's regulations to be served upon the party shall instead be served upon the representative.

(b) A party may choose any representative so long as the person is willing and available to serve. However, the other party or parties may challenge the representative on the grounds of conflict of interest or conflict of position. This challenge must be made by motion to the administrative judge within 10 days of service of the notice of designation, and shall be ruled upon by the administrative judge prior to any further proceeding in the case. These procedures apply equally to original and subsequent designations of representatives. In the event the selected representative is disqualified, the party affected shall be given a reasonable time to obtain another representative.

(c) The administrative judge, on his or her own motion, may disqualify a party's representative on the grounds described in paragraph (b) of this section.

§ 28.26 Witness fees.

The costs involved in the appearance of witnesses in any Board proceeding shall be allocated as follows:

(a) Persons employed by the GAO shall, upon request by the administrative judge to GAO, be made available to participate in the hearing and shall be in official duty status for this purpose and shall not receive witness fees. Payment of travel and per diem expenses shall be governed by applicable laws and regulations.

(b) Employees of other federal agencies called to testify at a Board hearing shall, at the request of the administrative judge and with the approval of the employing agency, be in official duty status during any period of absence from their normal duties caused by their testimony, and shall not receive witness fees. Payment of travel and per diem expenses shall be governed by applicable laws and regulations. A party planning to call an employee of another federal agency as a witness shall promptly notify the administrative judge of the need to submit to the federal agency a request that the employee be granted official duty status. In the event that the employing agency refuses the request to release the employee-witness in an official duty status, the employee-witness may be paid a witness fee in accordance with paragraph (c) of this section.

(c) Witnesses who are not covered by paragraphs (a) or (b) of this section are entitled to the same witness fees as those paid to subpoenaed witnesses under 28 U.S.C. 1821. The fees shall be paid, in the first instance, by the party requesting the appearance of the witness, subject to a subsequent decision otherwise in accordance with § 28.89, concerning the award of attorneys fees and costs. Such fees shall be tendered to the witness at the time the subpoena is served, or, when the witness appears voluntarily, at the time of appearance. A federal agency or corporation is not required to tender witness fees in advance. Payment of travel and per diem expenses shall be governed by applicable law and regulation.

(d) When the General Counsel is the petitioner or is representing the petitioner, the General Counsel shall pay the witness fees and arrange for the travel and per diem expenses that are required by paragraph (c) of this section.

§ 28.27 Intervenors.

(a) Intervenors are persons who are allowed to participate in a proceeding because the proceeding, or its outcome, may affect their rights or duties.

(b) Any person may, by motion to the administrative judge, request permission to intervene. The motion shall state the reasons why the person should be permitted to intervene. A person alleged to have committed a prohibited personnel practice under 5 U.S.C. 2302(b) may request permission to intervene under this section.

(c) A motion for permission to intervene will be granted where a determination is made by the administrative judge or the Board that the requestor will be affected directly by the outcome of the proceeding. Denial of a motion for intervention may be appealed to the Board. Such an appeal shall be filed within 10 days of service of the denial of the motion to intervene.

(d) Intervenors who are granted permission to intervene will be considered full parties to the hearing and will have the same rights and duties as a party with two exceptions:

(1) Intervenors will not have an independent right to a hearing.

(2) Intervenors may participate in Board proceedings only on the issues affecting them, as determined by the administrative judge or Board.

§ 28.28 Substitution.

(a) If a petitioner dies or is otherwise unable to pursue the appeal, the action may be completed upon substitution of a proper party.

(b) A motion for substitution shall be filed by the proper party within 90 days after the death of the petitioner or other disabling event.

§ 28.29 Consolidation or joinder.

(a) *Explanation.* (1) Consolidation may occur where two or more parties have cases which should be united because they contain identical or similar issues or in such other circumstances as justice requires.

(2) Joinder may occur where one person has two or more appeals pending and they are united for consideration. For example, a single appellant who has one appeal pending challenging a 30-day suspension and another appeal pending challenging a subsequent dismissal might have the cases joined.

(b) *Action by administrative judge.* An administrative judge may consolidate or join cases on his or her own initiative or on the motion of a party if to do so would expedite processing of the cases and not adversely affect the interests of the parties.

Discovery

§ 28.40 Statement of purpose.

Proceedings before the Board shall be conducted as expeditiously as possible with due regard to the rights of the parties. Discovery is designed to enable a party to obtain relevant information needed for presentation of the party's case. These regulations are intended to provide a simple method of discovery. They will be interpreted and applied so as to avoid delay and to facilitate adjudication of the case. The parties are expected to initiate and complete needed discovery with a minimum of Board intervention.

§ 28.41 Explanation, scope and methods.

(a) *Explanation.* Discovery is the process apart from the hearing whereby a party may obtain relevant information from another person, including a party, which has not otherwise been provided. Relevant information includes information which appears reasonably calculated to lead to the discovery of admissible evidence. This information is obtained for the purpose of assisting the parties in developing, preparing, and presenting their cases. The Federal Rules of Civil Procedure may be used as a general guide for discovery practices in proceedings before the Board, except as to matters specifically covered by these regulations. The Federal Rules of Civil Procedure shall be interpreted as instructive rather than controlling.

(b) *Scope.* Any person may be examined pursuant to paragraph (c) of this section regarding any nonprivileged matter which is relevant to the issue under appeal, including the existence, description, nature, custody, condition and location of documents or other tangible things, and the identity and location of persons having knowledge of relevant facts. The information sought must appear reasonably calculated to lead to the discovery of admissible evidence.

(c) *Methods.* Discovery may be obtained by one or more of the methods provided under the Federal Rules of Civil Procedure, including written interrogatories, depositions, production of documents or things for inspection or copying, and requests for admission addressed to parties.

§ 28.42 Discovery procedures and protective orders.

(a) *Discovery from a party.* A party seeking discovery from another party shall initiate the process by serving a request for discovery on the other party. For purposes of discovery under these regulations, a party includes an intervenor.

(1) Each request for discovery shall state the time limit for responding, as prescribed in paragraph (d) of this section.

(2) In the case of a request for deposition of a party, reasonable notice

in writing shall be given to every party to the action. The notice shall:

(i) Specify the time and place of the taking of the deposition; and

(ii) Be served on the person to be deposed.

(3) When a request for discovery is directed to an officer or employee of GAO, the agency shall make the officer or employee available on official time for the purpose of responding to the request and shall assist the officer or employee as necessary in providing relevant information that is available to the agency.

(b) *Discovery from a nonparty.* Parties are encouraged to attempt to obtain voluntary discovery from nonparties whenever possible. A party seeking discovery from a nonparty may initiate the process by serving a request for discovery on that nonparty and on all other parties to the proceeding. When a party is unable to obtain voluntary cooperation, the party may request that the administrative judge issue a subpoena by following the procedures set forth in § 28.46.

(c) *Responses to discovery requests.* (1) A party shall answer a discovery request within the time provided by paragraph (d)(2) of this section either by furnishing to the requesting party the information or testimony requested or agreeing to make deponents available to testify within a reasonable time, or by stating an objection to the particular request and the reasons for objection, or by requesting a protective order.

(2) Upon failure or refusal of a party to respond in full to a discovery request, the requesting party may file with the administrative judge a motion to compel discovery. The time limits applicable to a motion to compel are set forth in paragraph (d)(4) of this section. A copy of the motion shall be served on the other parties. The motion shall be accompanied by:

(i) A copy of the original request served on the party from whom discovery was sought and a statement showing the relevancy and materiality of the information sought; and

(ii) A copy of the objections to discovery or, where appropriate, a verified statement that no response has been received.

(3) The party from whom discovery was sought shall respond to the motion to compel within the time limits set forth in paragraph (d)(4) of this section.

(d) *Time limits.* (1) Requests for discovery shall be served within 30 days after the service list is served by the Board on all parties.

(2) A party or nonparty shall respond to a discovery request within 20 days after service of the request on the party or nonparty. Any discovery requests following the initial request shall be served within 10 days of the date of service of the prior response, unless otherwise directed. Deposition witnesses shall give their testimony at the time and place stated in the notice of deposition-taking or in the subpoena, unless the parties agree otherwise.

(3) In responding to a discovery request, a party or nonparty shall respond as fully as possible, except to the extent that the party or nonparty objects to the discovery or requests a protective order. Any objection or request for a protective order shall be filed within the time limits set forth in paragraph (d)(2) of this section. Any objection shall be addressed to the party requesting discovery and shall state the particular grounds for the objection. Any request for a protective order shall state the grounds for the protective order and shall be served on the administrative judge and any other parties to the action. The administrative judge shall rule on the request for a protective order.

(4) Motions for an order compelling discovery shall be filed with the administrative judge within 10 days of the service of objections or within 10 days of the expiration of the time limits for response when no response or an alleged inadequate response is received. Opposition to a motion to compel must be filed with the administrative judge within 10 days of the date of service of the motion.

(5) Discovery shall be completed by the time designated by the administrative judge, but no later than 65 days after the filing of the appeal. A later date may be set by the administrative judge after due consideration of the particular situation including the dates set for hearing and closing of the case record.

§ 28.43 Compelling discovery.

(a) *Motion for an order compelling discovery.* Motions for orders compelling discovery shall be submitted to the administrative judge as set forth at § 28.42(c)(2) and (d)(4) above.

(b) *Content of order.* Any order issued may include, where appropriate:

(1) Provision for notice to the person to be deposed as to the time and place of such deposition.

(2) Such conditions or limitations concerning the conduct or scope of the proceedings or the subject matter as may be necessary to prevent undue delay or to protect any party or deponent from undue expense, embarrassment or oppression.

(3) Limitations upon the time for conducting depositions, answering written interrogatories, or producing documentary evidence.

(4) Other restrictions upon the discovery process as determined by the administrative judge.

(c) Failure to comply with an order compelling discovery may subject the noncomplying party to sanctions under § 28.24.

§ 28.44 Taking of depositions.

Depositions may be taken before any person not interested in the outcome of the proceedings who is authorized by law to administer oaths.

§ 28.45 Admission of facts and genuineness of documents.

(a) Any party may be served with requests for the admission of the genuineness of any relevant documents identified within the request or the truth of any relevant matters of fact or application of law to the facts as set forth in the request.

(b) Within the time period prescribed by § 28.42(d)(2), the party on whom the request is served must submit to the requesting party:

(1) A sworn statement specifically denying, admitting, or expressing a lack of knowledge after making reasonable inquiry regarding the specific matters on which an admission is requested; and/or

(2) An objection to the request for an admission, in whole or in part, on the grounds that the matters contained therein are privileged, irrelevant, or otherwise improper.

(c) Upon a failure or refusal of a party to respond to a request for admissions within the prescribed time period, the request shall be deemed admitted.

Subpoenas

§ 28.46 Motion for subpoena.

(a) *Authority to issue subpoenas.* Any member of the Board may issue subpoenas requiring the attendance and testimony of witnesses and the production of documentary or other evidence from any place in the United States or any territory or possession thereof, the Commonwealth of Puerto Rico, or the District of Columbia. Any member of the Board may order the taking of depositions or order responses to written interrogatories.

(b) *Motion.* A motion for the issuance of a subpoena requiring the attendance and testimony of witnesses or the production of documents or other evidence under § 28.46(a) shall be submitted to the administrative judge at least 15 days in advance of the date scheduled for the commencement of the hearing. If the subpoena is sought as part of the discovery process, the

motion shall be submitted to the administrative judge at least 15 days in advance of the date set for the attendance of the witness at a deposition or the production of documents.

(c) *Forms and showing.* Motions for subpoenas shall be submitted in writing to the administrative judge and shall specify with particularity the books, papers, or testimony desired and shall be supported by a showing of general relevance and reasonable scope and a statement of the facts expected to be proven thereby.

(d) *Rulings.* Where the administrative judge is not a Board member, the motion shall be referred with a recommendation for decision to a Board member. The Board member shall promptly rule on the request. Where the administrative judge is a Board member, he or she shall rule directly on the request.

§ 28.47 Motion to quash.

Any person against whom a subpoena is directed may file a motion to quash or limit the subpoena setting forth the reasons why the subpoena should not be complied with or why it should be limited in scope. This motion shall be filed with the administrative judge within 20 days after service of the subpoena.

§ 28.48 Service.

Service of a subpoena may be made by a United States Marshal or Deputy Marshal or by any person who is over 18 years of age and not a party to the proceeding.

§ 28.49 Return of service.

When service of a subpoena is effected by a person other than a United States Marshal or Deputy Marshal, that person shall certify on the return of service that service was made either:

(a) In person,

(b) By registered or certified mail, or

(c) By delivery to a responsible person (named) at the residence or place of business (as appropriate) of the person to be served.

§ 28.50 Enforcement.

If a person has been served with a Board subpoena but fails or refuses to comply with its terms, the party seeking compliance may file a written motion for enforcement with the administrative judge or make an oral motion for enforcement while on record at a hearing. The party shall present the return of service and, except where the witness was required to appear before the administrative judge, shall submit affidavit evidence of the failure or refusal to obey the subpoena. The Board may then request the appropriate United States district court to enforce the subpoena.

Hearings

§ 28.55 Scheduling the hearing.

The notice of initial hearing shall fix the date, time and place of hearing. GAO, upon request of the administrative judge, shall provide appropriate hearing space. Motions for postponement by either party shall be made in writing, shall set forth the reasons for the request and shall be granted only upon a showing of good cause. When the parties agree on postponement, motions may be made orally and shall be granted only upon a showing of good cause.

§ 28.56 Hearing procedures, conduct and copies of exhibits.

(a) The Board may designate one or more administrative judges to conduct hearings on appropriate matters.

(b) The hearing will be conducted as an administrative proceeding and, ordinarily, the rules of evidence will not be strictly followed.

(c) Parties will be expected to present their cases in a concise manner limiting the testimony of witnesses and submission of documents to relevant matters.

(d) Any party to a hearing offering exhibits into the record shall submit the original of each such exhibit to the court reporter, two copies to the administrative judge, plus one copy for each opposing party that is separately represented.

(e) Each party to a proceeding shall be responsible for bringing the proper number of copies of an exhibit to the hearing.

(f) Multipage exhibits shall be paginated in the lower right hand corner and the first page shall indicate the total number of pages in the exhibit.

(g) No later than the commencement of the hearing, each party shall submit to the administrative judge, to the court reporter, and to the opposing party: (1) A typed list of the witnesses expected to be called to testify; and (2) a typed list of the acronyms (with definitions) expected to be used by the witnesses.

§ 28.57 Public hearings.

(a) Hearings shall be open to the public. However, the administrative judge at his or her discretion, may order a hearing or any part thereof closed, where to do so would be in the best interests of the petitioner, a witness, the public, or other affected persons. Any order closing the hearing shall set forth the reasons for the administrative judge's decision. Any objections thereto shall be made a part of the record.

(b) Regardless of whether a hearing is open or closed, the GAO technical representative, who is not expected to testify, the GAO representative, the petitioner and the petitioner's representative each has a right to be present at the hearing.

§ 28.58 Transcript.

(a) *Preparation.* A verbatim record made under supervision of the administrative judge shall be kept of every hearing and shall be the sole official record of the proceeding. Upon request, a copy of a transcript of the hearing shall be made available to each party. Additional copies of the transcript shall be made available to a party upon payment of costs. Exceptions to the payment requirement may be granted for good cause shown. A motion for an exception shall be made in writing and accompanied by an affidavit setting forth the reasons for the request and shall be granted upon a showing of good cause. Requests for copies of transcripts shall be directed to the Clerk of the Board. The Clerk of the Board may, by agreement with the person making the request, make arrangements with the official hearing reporter for required services to be charged to the requester.

(b) *Corrections.* Corrections to the official transcript will be permitted. Motions for correction must be submitted within 30 days of service of the transcript upon the party. Corrections of the official transcript will be permitted only when errors of substance are involved and only upon approval of the administrative judge. The administrative judge may make changes at any time with notice to the parties.

§ 28.59 Official record.

The transcript of testimony and the exhibits, together with all papers and motions filed in the proceedings, shall constitute the exclusive and official record.

§ 28.60 Briefs.

(a) *Length.* Principal briefs shall not exceed 60 pages and reply briefs 30 pages, exclusive of tables and pages limited only to quotations of statutes, rules, and the like. Motions to file extended briefs shall be granted only for good cause shown. Briefs in excess of 10 pages shall include an index and a table of authorities.

(b) *Format.* Every brief must be easily readable. Pages must be 8½ x 11 inches with margins at least one inch on all sides. Typewritten briefs must have double spacing between each line of

text, except for quoted texts which may be single spaced.

(c) *Number of copies.* An original and 3 copies of each brief shall be filed with the administrative judge and one copy served on each party separately represented. When an action is before the full Board, an original and seven copies of each brief must be filed with the Board and one copy served on each party separately represented.

§ 28.61 Burden and degree of proof.

(a) In appealable actions, as defined by 5 U.S.C. 7701(a), agency action must be sustained by the Board if:

(1) It is a performance-based action and is supported by substantial evidence; or

(2) It is brought under any other provision of law, rule, or regulation as defined by 5 U.S.C. 7701(a) and is supported by a preponderance of evidence.

(b) Notwithstanding paragraph (a) of this section, the agency's decision may not be sustained if the petitioner:

(1) Shows harmful error in the application of the agency's procedures in arriving at such decision;

(2) Shows that the decision was based on any prohibited personnel practice described in 4 CFR 2.5; or

(3) Shows that the decision was not in accordance with law.

(c) In any other action within the Board's jurisdiction, the petitioner shall have the responsibility of presenting the evidence in support of the action and shall have the burden of proving the allegations of the appeal by a preponderance of the evidence.

(d) Definitions. For purposes of this section, the following definitions shall apply:

Harmful error means error by the agency in the application of its procedures which, in the absence or cure of the error, might have caused the agency to reach a conclusion different than the one reached. The burden is upon the petitioner to show that, based upon the record as a whole, the error was harmful, i.e., caused substantial harm or prejudice to his or her rights.

Preponderance of the evidence means that degree of relevant evidence which a reasonable person, considering the record as a whole, would accept as sufficient to support a conclusion that the matter asserted is more likely to be true than not true.

Substantial evidence means that degree of relevant evidence which a reasonable person, considering the record as a whole, might accept as adequate to support a conclusion, even though other reasonable persons might disagree. This is a lower standard of proof than preponderance of the evidence.

§ 28.62 Closing the record.

(a) When there is a hearing, the record shall be closed at the conclusion of the hearing. However, when the administrative judge allows the parties to submit argument, briefs or documents previously identified for introduction into evidence, the record shall be left open for such time as the administrative judge grants for that purpose.

(b) Once the record is closed, no additional evidence or argument shall be accepted into the record except upon a showing that new and material evidence has become available which was not available despite due diligence prior to the closing of the record. However, the administrative judge shall make part of the record any motions for attorney fees, any supporting documentation, and determinations thereon, and any approved correction to the transcript.

Evidence

§ 28.65 Service of documents.

Any document submitted with regard to any pleading, motion, or brief shall be served upon all parties to the proceeding.

§ 28.66 Admissibility.

Evidence or testimony may be excluded from consideration by the administrative judge if it is irrelevant, immaterial, or unduly repetitious.

§ 28.67 Production of statements.

After an individual has given evidence in a proceeding, any party may request a copy of any prior signed statement made by that individual which is relevant to the evidence given. If the party refuses to furnish the statement, the administrative judge may draw an adverse inference from the failure to produce or may exclude the relevant evidence given by the individual from consideration.

§ 28.68 Stipulations.

The parties may stipulate as to any matter of fact. Such a stipulation will satisfy a party's burden of proving the fact alleged.

§ 28.69 Judicial notice.

The administrative judge on his or her own motion or on motion of a party, may take judicial notice of a fact which is not subject to reasonable dispute because it is either: (a) A matter of common knowledge; or (b) capable of accurate and ready determination by resort to sources whose accuracy cannot reasonably be questioned. Judicial notice taken of any fact satisfies a party's burden of proving the fact noticed.

Interlocutory Appeals

§ 28.80 Explanation.

An interlocutory appeal is an appeal to the Board of a ruling made by an administrative judge during the course of a proceeding. This appeal may be permitted by the administrative judge if he or she determines that the issue presented is of such importance to the proceeding that it requires the Board's immediate attention. The Board makes a decision on the issue and the administrative judge acts in accordance with that decision.

§ 28.81 Procedures and criteria for certification.

(a) Interlocutory review by the Board of a ruling by the administrative judge during the course of the proceeding is disfavored and will be permitted only in circumstances where:

(1) The ruling involves an important question of law or policy about which there is substantial ground for difference of opinion; and

(2) An immediate review of the ruling by the Board will materially advance the completion of the proceeding, or denial will cause undue harm to a party or the public.

(b) The administrative judge may, on motion of a party or on his or her own motion, certify an interlocutory ruling to the Board for its immediate consideration. Any such certification shall explain the basis on which the administrative judge concluded that the standards for interlocutory review have been met. If the Board nevertheless determines that the certification does not meet those standards it may decline to accept the certification.

(c) A motion for certification to the Board of an interlocutory ruling by the administrative judge shall be filed within 10 days after service of the ruling upon the parties. The motion shall include arguments in support of both the certification and the determination to be made by the Board. Responses, if any, shall be filed within 10 days after service of the motion.

(d) The grant or denial of a motion for certification of an interlocutory ruling shall not be appealable. The administrative judge shall promptly bring a denial of such a motion, and the reasons therefor, to the attention of the Board. If, upon its consideration of the motion and the underlying record, the Board believes that interlocutory review is warranted, it may grant the motion sua sponte.

(e) Upon its acceptance of a ruling of the administrative judge for interlocutory review, the Board shall issue an order setting forth the procedures that will be followed in the conduct of that review.

(f) Unless otherwise directed by the Board, the stay of any proceedings during the pendency of either a motion for certification or an interlocutory review itself shall be within the discretion of the administrative judge.

(g) The denial of a motion for certification does not affect the right of the parties to challenge interlocutory rulings in the course of the review by the Board of initial or recommended decisions.

Board Decisions, Attorney's Fees and Judicial Review

§ 28.86 Board procedures; recommended decisions.

(a) *Non-member recommended decisions.* Where an administrative judge who is not a Board member issues a decision, the administrative judge shall transmit to the parties and to the Board a recommended decision.

(b) Exceptions to the recommended decision shall be filed within 30 days from service of the decision. Exceptions may be filed by hand delivery or by mail. Please note that the address to be used differs for the two kinds of filing.

(1) *Filing by hand delivery:* Exceptions may be filed by hand delivery at the office of the Board, suite 830, Union Center Plaza II, 820 First Street, NE., Washington, DC.

(2) *Filing by mail:* Exceptions may be filed by mail addressed to the Personnel Appeals Board, suite 830, Union Center Plaza II, 441 G Street, NW., Washington, DC 20548. When filed by mail, the postmark shall be the exclusive date of filing.

The party filing the exceptions shall serve the Board with an original and 7 copies and shall serve one copy of the exceptions on each of the other parties. The exceptions shall include all supporting material and shall set forth objections to the recommended decision, with references to applicable laws or regulations, and with specific reference to the record. The responding party shall have 30 days from service of the exceptions to file any reply. Additional responsive pleadings may be filed only with the approval of the Board.

(c) Regardless of whether exceptions to a recommended decision are filed with the Board, the Board shall review the recommended decision. In reviewing the recommended decision, the Board shall review the record as though it were making the initial decision. The Board may adopt, reverse, remand, modify or vacate the recommended decision, in whole or in part. Where no party files exceptions to a recommended decision and the Board is considering any action other than adopting the recommended decision in whole as the final decision, the Board shall provide the parties an opportunity to address the issues it is considering. Where appropriate, the Board shall issue a final decision and order a date for compliance. In reviewing any recommended decision, the Board may:

(1) Issue a single decision which decides the case;

(2) Hear oral arguments;

(3) Require the filing of briefs;

(4) Remand the proceedings to the administrative judge to take further testimony or evidence or make further findings or conclusions; or

(5) Take any other action necessary for final disposition of the case.

(d) The Board shall reject a recommended decision, in whole or in part, on the basis of its own motion or on the basis of exceptions filed by the parties, when the Board finds that:

(1) New and material evidence is available that, despite due diligence, was not available when the record was closed;

(2) The recommended decision is based on an erroneous interpretation of statute or regulation;

(3) The recommended decision is arbitrary, capricious or an abuse of discretion, or otherwise not consistent with law;

(4) The recommended decision is not made consistent with required procedures and results in harmful error; or

(5) The recommended decision is unsupported by evidence required by the requisite burden of proof as set forth at § 28.61.

(e) The decision of the Board shall be final and subject to judicial review pursuant to § 28.90.

§ 28.87 Board procedures; initial decisions.

(a) When a case is heard in the first instance by a single Board member, or a panel of members, an initial decision shall be issued by that member or panel and served upon the parties.

(b) An aggrieved party may seek review or reconsideration of the initial decision in the following manner:

(1) Within 15 days of the service of the initial decision, such a party may seek review by the full Board by filing and serving a notice of appeal to the Board.

(2) Within 10 days of the service of the initial decision, such a party may file and serve a request for reconsideration with the administrative judge or panel rendering that decision. Filing of the request for reconsideration shall toll the commencement of the 15 day period for filing a notice of appeal with the full Board, pending disposition of the request for reconsideration by the administrative judge or panel. The administrative judge or panel shall determine if a response is required, and if so, will fix by order the time for the filing of the response. A motion for reconsideration will not be granted without providing an opportunity for response.

(c) Within 25 days following the filing of a notice of appeal to the full Board, the appellant shall file and serve a supporting brief. That brief shall identify with particularity those findings or conclusions in the initial decision that are challenged and shall refer specifically to the portions of the record and the provisions of statutes or regulations that assertedly support each assignment of error. Within 25 days following the service of the appellant's brief, the appellee may file and serve a responsive brief. Within 10 days following the service of the appellee's responsive brief, the appellant may file and serve a reply brief.

(d) In the absence of a timely appeal, the initial decision shall become the final decision of the Board 30 days following its issuance or the date of the administrative judge's or panel's disposition of a request for reconsideration (whichever comes later) unless, prior to the expiration of the 30 day period, the parties are notified in writing that the full Board intends to review the initial decision in whole or in part on its own motion. Such review sua sponte will normally be conducted only if a majority of the Board concludes that one or more issues of law addressed in the initial decision are of such importance as to warrant consideration by the full Board notwithstanding the absence of appeal. Issues so qualifying shall be identified in the Board's notice and the parties shall be provided an opportunity to brief them prior to the Board's decision.

(e) Oral argument on an appeal or in connection with a sua sponte review shall be held in the discretion of the Board. Any party may request that the Board exercise its discretion in that regard.

(f) Upon appeal or following its review sua sponte, the Board may affirm, reverse, modify or vacate the initial decision in whole or in part. If deemed warranted, the Board may remand the proceeding to the single member or panel for further action,

including the reopening of the record for the taking of additional evidence. Unless the full Board expressly retains jurisdiction, the single member or panel shall render, on completion of the remand, a supplemental initial decision which shall be subject to appellate review in the same manner and to the same extent as provided for initial decisions in paragraphs (b), (d) and (g) of this section. If the Board does expressly retain jurisdiction at the time of remand, the single member or panel shall instead render a report to the Board on the remanded matters. Upon receipt of the report, the Board shall determine whether the views of the parties on the content of the report should be obtained in writing and, where necessary, shall fix by order the time for the submission of those views. A decision of the full Board disposing of the proceeding without a remand or, where the Board has expressly retained jurisdiction, following completion of the remand shall be the final decision of the Board and subject to judicial review.

(g) In conducting its examination of the initial decision, the Board may review the record as though it were making the initial decision itself. As a general matter, however, the Board will not overturn a finding of fact contained in the initial decision unless that finding is unsupported by substantial evidence in the record viewed as a whole. In determining whether some action other than affirmance of the initial decision is required, the Board will also consider whether:

(1) New and material evidence is available that, despite due diligence, was not available when the record was closed;

(2) The initial decision is based on an erroneous interpretation of statute or regulation;

(3) The initial decision is arbitrary, capricious or an abuse of discretion, or otherwise not consistent with law;

(4) The initial decision is not made consistent with required procedures and results in harmful error.

(h) Initial decisions that become final without review by the full Board shall not be binding precedent in any other case.

§ 28.88 Board procedures; enforcement.

(a) A person required to take any action under the terms of a Board decision or order shall carry out its terms promptly, and shall, within 30 days after the decision or order becomes final, provide the Board and all parties to the proceeding with a compliance report specifying:

(1) The manner in which compliance with the provisions of the decision or order has been accomplished;

(2) The reasons why compliance with any provisions of the Board's order has not been fully accomplished; and

(3) The steps being taken to ensure full compliance.

(b) When the Board does not receive a notice of compliance in accordance with paragraph (a) of this section, the Solicitor shall make inquiries to determine the status of the compliance report. When the Solicitor establishes that a complete compliance report is not forthcoming, the Solicitor shall report the failure to file a complete compliance report to the Board.

(c) Any person and/or the General Counsel may petition the Board for enforcement of a final decision of the Board. The petition shall specifically set forth the reasons why the petitioner believes there is non-compliance.

(d) Upon receipt of a non-compliance report from its Solicitor or of a petition for enforcement of a final decision, the Board may issue a notice to any person to show cause why there was non-compliance. Following a show cause proceeding, the Board may seek judicial enforcement of its decision or order.

§ 28.89 Attorney's fees and costs.

Within 20 days after service of a final decision by the Board, or within 20 days after the date on which an initial decision becomes final pursuant to § 28.87(d), the petitioner, if he or she is the prevailing party, may submit to the administrative judge who heard the case initially a request for the award of reasonable attorney fees and costs. GAO may file a response within 20 days after service of the request. Motions for attorney fees shall be filed in accordance with § 28.21 of these regulations. Rulings on attorney's fees and costs shall be consistent with the standards set forth at 5 U.S.C. 7701(g). The decision of the administrative judge concerning attorney's fees and costs shall be subject to review and shall become final according to the provisions of §§ 28.86–28.87.

§ 28.90 Board procedures; judicial review.

(a) A final decision by the Board under 31 U.S.C. 753(a) (1), (2), (3), (6), or (7) may be appealed to the United States Court of Appeals for the Federal Circuit within 30 days after the petitioner receives notice of the Board's decision.

(b) Special provisions regarding civil actions in discrimination cases are set forth at § 28.100.

(c) The Board may designate the Solicitor, the General Counsel or any other qualified individual to represent it in any judicial proceeding involving a Board decision or the interpretation of a Board rule or of the GAO Personnel Act.

Subpart C—Oversight Procedures

§ 28.91 General.

Pursuant to section 732(f) of Title 31, U.S.C., the Board is authorized to conduct oversight of GAO employment regulations, procedures and practices as they relate to laws prohibiting discrimination in employment on the basis of race, color, religion, national origin, political affiliation, age, sex, marital status, or disability.

§ 28.92 Oversight of GAO EEO program.

(a) When requested by the Board in the exercise of its oversight responsibility, GAO shall provide:

(1) Such plans, procedures and regulations as GAO may develop in order to eliminate and prevent employment discrimination on the bases enumerated in § 28.95;

(2) Reports regarding its efforts to publicize to its employees the procedures to be followed for receiving advice and for filing complaints regarding the enforcement of laws prohibiting discrimination in employment;

(3) Quarterly statistical reports of pre-complaint counseling and of pending complaints, in a manner prescribed by the Board;

(4) An annual report on its equal employment opportunity affirmative action program and its Federal Equal Employment Opportunity Recruitment Program; and

(5) Any other information regarding equal employment opportunity within the GAO that may be required by the Board, in the time frame and format established by the Board after consultation with the Comptroller General or his or her designee.

(b) The Board shall review and evaluate the regulations, procedures and practices of the GAO, including the information filed with it in accordance with paragraph (a) above, and shall:

(1) Require the GAO to make any changes the Board determines are needed due to violations of or inconsistencies with Subchapters III and IV of Chapter 7 of Title 31, U.S.C. or equal employment opportunity laws, and

(2) Report to the Congress on the overall progress being made in effectuating the purposes of Subchapters III and IV of Chapter 7 of Title 31, U.S.C.

Subpart D—Special Procedures; Equal Employment Opportunity (EEO) Cases

§ 28.95 Purpose and scope.

The procedures in this subpart relate to charges filed against any GAO policies or specific actions which are alleged to involve prohibited discrimination. Prohibited discrimination is defined as any action in violation of:

(a) Section 717 of the Civil Rights Act of 1964 (42 U.S.C. 2000e–16), prohibiting discrimination based on race, color, religion, sex or national origin;

(b) Sections 12 and 15 of the Age Discrimination in Employment Act of 1967 (29 U.S.C. 631, 633a) prohibiting discrimination on account of age;

(c) Section 6(d) of the Fair Labor Standards Act of 1938 (29 U.S.C. 206(d), prohibiting discrimination in wages on the basis of sex;

(d) Sections 501 and 505 of the Rehabilitation Act of 1973 (29 U.S.C. 791, 794a) prohibiting discrimination on the basis of disability; or

(e) Any other law prohibiting discrimination in Federal employment on the basis of race, color, religion, age, sex, national origin or disability. 31 U.S.C. 732(f)(2).

§ 28.96 Applicability of general procedures.

Except where a different procedure is provided for in this subpart, the procedures to be followed by all parties in cases arising under this subpart shall be the general procedures as prescribed in subpart B of this part.

§ 28.97 Class actions in EEO cases.

(a) Prior to invoking the Board's procedures in a case alleging prohibited discrimination on behalf of a class of GAO employees or applicants for employment, a complaint must first be filed with GAO in accordance with GAO Order 2713.2.

(b) A petition for review of GAO's disposition of any EEO class complaint may be submitted to the Board at the following times:

(1) Within 20 days of receipt of a GAO determination rejecting or canceling the class complaint;

(2) Within 20 days of receipt of a GAO determination accepting the class action, but with modifications that are not satisfactory to the agent of the class;

(3) When a period of more than 180 days has elapsed since the formal class complaint was filed and the GAO has not issued a final decision; or

(4) Within 20 days of receipt of a final GAO decision resolving the complaint if that decision, in whole or in part, has not satisfied the agent for the class.

(c) In class actions in EEO cases, no charge shall be filed or investigated by the General Counsel prior to filing a petition for review with the Board. However, the General Counsel may request permission to intervene with regard to any issue in which the General Counsel finds a significant public interest with respect to the preservation of the merit system.

(d) The parties shall not have a right to a hearing on a petition for review in class actions under this section. Upon a showing of good cause as to why an evidentiary hearing is necessary, the Board may order such a hearing. Alternatively, the Board may, after a review of the administrative record and on its own motion, order a hearing for the purpose of gathering additional evidence. If no hearing is ordered, the Board's decision shall be based upon a review of the administrative record developed in the GAO class complaint process.

(e) Standards. For the purpose of determining whether it is appropriate to treat an appeal as a class action, the administrative judge will be guided, but not controlled, by the applicable provisions of the Federal Rules of Civil Procedure.

§ 28.98 Individual charges in EEO cases.

(a) Except as provided in paragraph (c) of this section, a charge alleging prohibited discrimination (as defined in § 28.95) shall not be filed with the Board's General Counsel unless the charging party has first filed a complaint of discrimination with GAO in accordance with GAO Order 2713.2.

(b) A charge relating to GAO's disposition of any individual EEO complaint may be filed with the Board's General Counsel at the following times:

(1) Within 20 days from the receipt by the charging party of a GAO decision rejecting the complaint in whole or part.

(2) Whenever a period of more than 120 days has elapsed since the complaint was filed, and the GAO has not issued a final decision; or

(3) Within 20 days from the receipt by the charging party of a final GAO decision concerning the complaint of discrimination.

(c) Special rules for adverse and performance-based actions. Where an employee is affected by a removal, suspension for more than 14 days, reduction in grade or pay, or furlough of not more than 30 days (whether due to disciplinary, performance-based or other reasons), and the employee wishes to allege that such action was due in whole or part to prohibited discrimination (as defined in § 28.95), the employee may elect to do either (but not both) of the following:

(1) File a charge directly with the Board's General Counsel within 20 days of the effective date of the personnel action and raise the issue of discrimination in the course of the proceedings before the Board; or

(2) File a complaint of discrimination with the GAO pursuant to GAO Order 2713.2. If the employee elects to file a complaint of discrimination with GAO, he or she may still seek Board review of the matter by filing a charge with the Board's General Counsel at the times authorized in paragraph (b) of this section. Where a complaint of discrimination filed with GAO relates to non-EEO issues that are within the Board's jurisdiction in addition to EEO-related allegations, the subsequent charge filed with the Board's General Counsel under paragraph (b) of this section shall be considered a timely appeal of the non-EEO issues. An employee will be deemed to have elected the EEO complaint process if the employee files a timely written complaint of discrimination with GAO before filing a charge with the Board's General Counsel. Consultation with an EEO counselor, without filing a written complaint of discrimination, does not constitute an election of the EEO complaint process.

(d) The charging party shall file the charge with the General Counsel in accordance with § 28.11. The General Counsel shall investigate the charge in accordance with § 28.12.

§ 28.99 Petitions for review to the Board in EEO cases.

(a) The provisions of §§ 28.18 through 28.90, inclusive, shall govern the Board's procedures in processing petitions filed under this subpart.

(b) Remedial action provided in Board orders in these cases may include:

(1) Provision for offers of employment, re-employment or promotion, with or without back pay, when the Board decides such action is required to make whole the individual found to have been discriminated against.

(2) Notification to all GAO employees of the action ordered to be taken to expunge the effect of the discrimination;

(3) Correction of GAO personnel records, as necessary, to reflect the purpose of the Board order; and,

(4) Any other action the Board believes proper to correct the effect of the discrimination found to have occurred.

§ 28.100 Civil action; discrimination complaints.

(a) *Race, color, religion, sex, or national origin.* An employee or applicant alleging violations of 42 U.S.C. 2000e–16 (Title VII of the Civil Rights Act of 1964, as amended) may file suit in Federal District Court—

(1) After 180 days from filing a complaint with GAO if there is no final decision on that complaint or within 90 days of receipt of notice of final action taken by GAO, or

(2) After 180 days from filing a charge with the General Counsel if there is no final decision by the Board on that discrimination appeal or within 90 days of receipt of notice of final action by the Board.

(b) *Disability.* An employee or applicant alleging discrimination based upon disability (29 U.S.C. 791, 794a, Rehabilitation Act) may file suit in Federal District Court—

(1) After 180 days from filing a complaint with GAO if there is no final decision on that complaint or within 90 days of receipt of notice of final action taken by GAO, or

(2) After 180 days from filing a charge with the General Counsel, if there is no final decision by the Board on that discrimination appeal or within 90 days of receipt of notice of final action by the Board.

(c) *Age.* An employee or applicant alleging discrimination based upon age (29 U.S.C. 631, 633a, Age Discrimination in Employment Act) may forego administrative action altogether and file a civil action in U.S. District Court after giving GAO 30 days Notice of Intent to File such action. The Notice shall be filed within 180 days after the alleged unlawful practice occurred. When such notice is provided and no administrative complaint is filed, a civil action may be filed in the appropriate U.S. District Court within two years or, if the violation is willful, three years of the date of the alleged ADEA violation. An employee or applicant for employment, who has filed an administrative complaint alleging age discrimination, may file suit in Federal District Court—

(1) After 180 days from filing a complaint with GAO if there is no final decision on that complaint or within 90 days of receipt of notice of final action taken by GAO, or

(2) After 180 days from filing a charge with the General Counsel if there is no final decision by the Board on that discrimination appeal or within 90 days of receipt of notice of final action by the Board.

(d) *Sex-based salary inequity.* An employee or applicant alleging discrimination based upon salary inequity due to sex (29 U.S.C. 206d, Equal Pay Act provision of the Fair Labor Standards Act) may forego administrative action altogether and file suit in U.S. District Court.

(e) In lieu of filing a civil action in U.S. District Court, a final decision of the Board involving prohibited discrimination (31 U.S.C. 732(f)(1)) may be appealed, in accordance with 31 U.S.C. 755, to the United States Court of Appeals for the Federal Circuit within 30 days after the date the petitioner receives notice from the Board of the final decision.

§ 28.101 Effect on administrative processing.

Any proceeding before the Board shall be terminated when an employee or applicant who is alleging violations of Title VII of the Civil Rights Act of 1964, as amended, 42 U.S.C. 2000e–16, or who is alleging violations of the Rehabilitation Act, 29 U.S.C. 791, or who is alleging age discrimination (29 U.S.C. 631, 633a) files suit in Federal District Court pursuant to § 28.100 (a), (b) or (c).

Subpart E—Special Procedures; Representation Proceedings

§ 28.110 Purpose.

The procedures in this subpart relate to the Board's duty under 31 U.S.C. 753(a) (4) and (5) to determine appropriate units of GAO employees for collective bargaining, to conduct elections in order to determine whether the employees in any such units wish to select a labor organization to represent them in collective bargaining, and, thereafter, to certify labor organizations so selected as the designated exclusive bargaining representative. They are referred to in these regulations as "representation proceedings".

§ 28.111 Scope.

The Board shall consider, decide and order corrective action (as appropriate) in cases arising from the determination of appropriate units of employment for collective bargaining and cases arising from elections and certifications of collective bargaining representatives. Board decisions in these matters will be made with due regard for relevant provisions of GAO Orders and with the objective of insuring that the GAO labor relations program is consistent with Chapter 71 of Title 5, United States Code, which prescribes the standards for the labor relations program in the executive branch.

§ 28.112 Who may file petitions.

(a) Representation petitions may be filed by:

(1) A labor organization which wishes to be designated as the exclusive representative for collective bargaining by the GAO employees in an appropriate unit, or by a labor organization which desires to replace another currently having that status;

(2) An employee or a group of employees (or an individual on his, her or their behalf) desiring a new election to determine whether a labor organization has ceased to represent a majority of employees in a unit;

(3) The GAO if it has a good faith reason to doubt the continued desire of a group of its employees to be represented by a labor organization which is currently the exclusive representative of the employees in an appropriate unit;

(4) The GAO or a labor organization currently recognized as an exclusive representative desiring the Board to clarify an earlier unit determination or certification;

(5) Any person seeking clarification of, or an amendment to, a certification then in effect or any other matter relating to representation.

(b) Notwithstanding the provisions of paragraph (a) of this section, no petition may be filed which seeks representation rights for employees in a unit—

(1) Where an election has been held within the previous 12 calendar months and in such election a majority of the employees voting chose a labor organization for certification as the unit's exclusive representative, or

(2) Where an existing collective bargaining agreement having a term of three years or less is in effect, unless the petition for exclusive recognition is filed not more than 105 days and not less than 60 days before the expiration of the collective bargaining agreement, or

(3) Where an existing collective bargaining agreement having a term of more than three years is in effect, unless the petition for recognition is filed not more than 105 days and not less than 60 days before the third anniversary or any subsequent anniversary of the collective bargaining agreement.

§ 28.113 Contents of representation petitions.

(a) The contents of representation petitions filed under § 28.112(a)(1) (by a labor organization seeking to be designated as or replace an exclusive bargaining representative) shall consist of:

(1) A detailed identification of the unit of employees to which the petition

applies, and their geographical location within the GAO, the classifications of employees to be included and excluded, and the number of employees involved;

(2) Names, addresses and officers of any other labor organizations known by the petitioner to be interested in representing employees covered by the petition, including a labor organization which is party to a current collective bargaining agreement covering any employees in the unit;

(3) Name, address, affiliation, if any, and telephone number of the petitioning organization;

(4) A copy of the constitution and bylaws of the organization, a roster of the organization's officers and representatives, and a statement of the organization's objectives, together with a statement that these documents have also been supplied to the GAO;

(5) A declaration by the signer of the petition, under penalties of the Criminal Code (18 U.S.C. 1101), that the petition's contents are true and correct, to the best of his or her knowledge and belief;

(6) The signature of the representative of the petitioner, including title and telephone number; and

(7) Membership cards, dues records, or signed statements by employees indicating their desire to be represented by the labor organization, or similar evidence acceptable to the Board, showing that at least 30 percent of the employees in the proposed unit wish to be represented by the petitioner.

(b) The contents of petitions filed under § 28.112(a)(2) (by an employee or group of employees seeking an election to determine if a labor organization still represents a majority of employees in a unit) shall conform to those provided for in paragraph (a) of this section, except that the information required by paragraphs (a)(4) and (a)(7) of this section need not be supplied. Additionally, a petition under § 28.112(a)(2) shall include evidence satisfactory to the Board that at least 30 percent of the employees in the unit no longer wish to be represented by the labor organization currently having bargaining rights.

(c) The contents of petitions filed under § 28.112(a)(3) (by GAO raising good faith doubts about the continued desire of a group of its employees to be represented by a labor organization) shall conform to those provided in petitions under paragraph (a) of this section except that the information required by paragraphs (a)(4) and (a)(7) of this section need not be supplied. Additionally, such a petition shall include a detailed statement giving the objective considerations which support the GAO's good faith reason for doubting the labor organization's continued status as the exclusive representative.

(d) The contents of petitions filed under § 28.112(a)(4) (by GAO or a labor organization seeking clarification of a certification) shall include the information required under paragraph (a) of this section, with the exception of the information required by paragraphs (a)(4) and (a)(7) of this section. Also, instead of the information required in paragraph (a)(1) of this section, the petition shall identify the existing unit and the date the organization was recognized by the GAO or certified as the exclusive representative, and shall explain the changes desired in the unit and the reasons therefor.

(e) Petitions under § 28.112(a)(5) (by any person seeking clarification or amendment of a certification, or raising any other representation matter) shall be filed on forms to be supplied by the Board upon request.

§ 28.114 Pre-investigation proceedings.

(a) Upon the filing of a valid petition, the General Counsel may request GAO to notify employees as to the existence of the petition by posting a notice for at least 10 days in locations appropriately selected to reach all employees in the unit covered by the petition. The notice shall include a request that the Board's General Counsel be notified of the existence of any other interested parties.

(b) GAO shall supply the General Counsel with any information in its possession concerning other potentially interested labor organizations, copies of relevant correspondence, and copies of existing or recently expired agreements covering any employees in the unit. The GAO shall also provide a list of employees it believes should be included in the unit together with their classifications and the names and classifications of those employees it proposes to exclude from the unit.

(c) All interested parties shall meet as soon as possible after the expiration of the 10-day posting period and shall attempt to resolve any issues in controversy.

(d) A labor organization may become an intervenor in any representation proceeding by submitting to the General Counsel, within the 10-day period, evidence that it represents at least 10 percent of the employees in the proposed unit or that it is the exclusive representative of the employees involved. Denial of a request to intervene may be appealed to the Board. Such an appeal must be filed within 10 days of service of the General Counsel's determination.

§ 28.115 Processing petitions.

(a) Upon the expiration of the 10-day posting period, and after the General Counsel considers an appropriate period has elapsed for consultation among the parties to resolve or identify issues, the General Counsel shall prepare a report to the Board which may recommend:

(1) Approval of any agreement entered into by the parties during their consultations including an agreement on the appropriate units, on the withdrawal of the petition, or on a joint request to conduct an election to determine which labor organization, if any, the employees select to be their exclusive bargaining representative;

(2) Dismissal of the petition as being without merit; or

(3) Issuance of a notice of hearing for the purpose of disposing of the remaining issues raised in the petition.

(b) The General Counsel's report shall be supplied to all interested parties, and, unless all parties agree to a shorter period, they shall have 15 days during which to file any response with the Board.

(c) The Board, as expeditiously as feasible after the expiration of the period specified in paragraph (b) of this section, but no later than 30 days thereafter, shall either approve the report and order appropriate steps to carry out its recommendations, or remand it to the General Counsel with further instructions.

(d) Where a hearing is ordered, an administrative judge shall be designated by the Board. The report of the administrative judge shall include Findings of Fact and Recommendations.

(e) After receiving the report from the administrative judge, and after providing the parties with an opportunity for comment, the Board shall issue a Decision and Order determining the appropriate unit, directing an election, dismissing the petition or making some other appropriate disposition of the matter.

(f) Final Decisions and Orders issued by the Board based on hearings held in accordance with paragraphs (d) and (e) of this section shall not be considered final decisions subject to appeal before the Circuit Courts of Appeal.

§ 28.116 Conduct of elections.

(a) The Board shall supervise any election it orders to be conducted, but may delegate ministerial functions relating to an election to any qualified independent organization; to members of the Board's full-time staff; or to temporary employees hired for this purpose.

(b) Appropriate notices setting forth details of the election shall be posted by GAO as directed by the Board.

(c) The Board shall, through its agents chosen to conduct the election:

(1) Provide the opportunity for all qualified voters to indicate their choices in secrecy;

(2) Offer qualified voters the opportunity to vote for any labor organization on the ballot, or to reject all labor organizations;

(3) Permit all parties to observe all aspects of the election procedure other than any which would interfere with the secrecy of the ballot;

(4) Provide for all parties to challenge the eligibility of any voters, and to impound the ballots of such voters, subject to later determination of eligibility should the number of challenges potentially affect the results;

(5) Certify to all parties the results of the election.

(d) Upon receiving a report of the results of the election, the Board shall:

(1) If necessary rule on the challenges and adjust the results accordingly;

(2) Formally announce the results and, where appropriate, designate a labor organization as the exclusive collective bargaining agent, or withdraw such a designation;

(3) Order a runoff or an additional election, if the Board deems it appropriate, where the results of the original election are inconclusive because no choice on the ballot has secured a majority of the valid votes cast. Not more than one additional and one runoff election may be held.

(i) *Runoff election.* The Board may order a runoff election where one or more of the labor organizations on the ballot has received the vote of at least 30 percent of the employees eligible to vote, but none has gained a majority of the votes cast. The runoff election will be between the two choices receiving the largest and the second largest number of votes in the original election.

(ii) *Additional election.* The Board may order an additional election where there is a tie vote between all of the choices on the ballot or where a runoff election is not feasible because there is a tie between the choices receiving the second most votes in the original election. The additional election will include all the choices that appeared on the original ballot.

Subpart F—Special Procedures; Unfair Labor Practices

§ 28.120 Authority of the Board.

(a) The procedures in this subpart relate in part to the Board's function, under 31 U.S.C. 753(a)(6), to "consider and order corrective or disciplinary action in a case arising from * * * a matter appealable to the Board under the labor-management relations program under (31 U.S.C. 732(e)(2)) including a labor practice prohibited under (31 U.S.C. 732(e)(1))."

(b) The system so established by the Comptroller General is required to provide that each employee of the GAO has the right to form, join or assist, or not form, join or assist an employee organization, freely and without penalty or reprisal, and for a labor-management relations program consistent with Chapter 71 of Title 5, U.S.C. (31 U.S.C. 732(e)).

§ 28.121 Unfair labor practices; Board procedures.

(a) Unfair labor practices are defined at GAO Order 2711.1. An allegation that a provision of GAO Order 2711.1 is inconsistent with Chapter 71 of Title 5, United States Code, and thereby denies to an employee or labor organization rights comparable to those granted by Chapter 71 of Title 5, United States Code, may also be raised under the unfair labor practice procedure.

(b) An allegation that unfair labor practices have been committed shall be subject to the procedures appearing in subpart B of this part for the filing of charges, investigation by the General Counsel, and the Board's disposition, except as set forth in paragraphs (c) and (d) of this section.

(c) Except as provided in paragraph (d) of this section, no petition for review may be filed based on any alleged unfair labor practice which occurred more than 6 months before the filing of an unfair labor practice charge with the charged party, as provided in paragraph 14b of GAO Order 2711.1, or more than 9 months before the filing of a charge with the General Counsel.

(d) If the Board determines that the charging party was prevented from filing the charge during the 6-month period referred to in paragraph (c) of this section by reason of:

(1) Any failure of the charged party to perform a duty owed to the charging party; or

(2) Any concealment which prevented discovery of the alleged unfair labor practice during the 6-month period; the charge will be considered timely filed, provided it was filed with the charged party during the 6-month period beginning on the day of the discovery of the alleged unfair labor practice by the charging party.

§ 28.122 Negotiability issues; compelling need.

Where the GAO and an exclusive bargaining representative disagree on whether a matter is subject to negotiation as part of the requirement to bargain in good faith, the matter shall be appealable to the Board under the following procedures:

(a) When, in connection with negotiations, a proposal is declared nonnegotiable, the party submitting the proposal shall, prior to the close of negotiations, submit to the other party a Request for Formal Negotiability Determination reciting the proposal in question. The party declaring the proposal nonnegotiable shall, within ten (10) days, deliver to the other party a Formal Negotiability Determination stating the basis for the Determination.

(b) A Formal Negotiability Determination may be appealed to the Board within 20 days of its service by filing a Petition for Review with the Board. A complete statement of argument from the petitioner should accompany the Petition for Review.

(c) The Board shall serve the Respondent with a copy of the Petition for Review and accompanying argument. Respondent shall reply to the Petition for Review within 20 days of its service upon respondent.

(d) One or more members of the Board shall review the arguments, hold a hearing if the administrative judge deems it necessary, and issue a decision.

(e) The decision shall become final in accordance with §§ 28.86–28.87.

§ 28.123 Standards of conduct for labor organizations.

(a) The GAO shall only accord recognition to labor organizations that are free from corrupt influences and from influences opposed to basic democratic principles. An organization is not required to prove it is free from such influence if it is subject to governing requirements calling for the maintenance of:

(1) Democratic procedures;

(2) Freedom from totalitarian influence;

(3) Independence on the part of its agents and officers from any business or financial interests which represent conflicts of interest or potential conflicts of interest; and

(4) Fiscal integrity, including provision for the dissemination of regular financial reports to its members.

(b) A labor organization which has or seeks recognition as a representative of employees under this chapter shall file financial and other reports with the Board and comply with trusteeship and election standards.

(c) A labor organization which has or seeks recognition under these Rules shall adhere to principles enunciated in

the Regulations issued by the Assistant Secretary of Labor for Labor/Management Relations regarding standards of conduct for labor organizations in the public sector. Complaints of violations of this section shall be filed with the Board. In any matter arising under this section, the Board may require a labor organization to cease and desist from violations of this section and require it to take such actions as it considers appropriate to carry out the policies of this section.

(d) This chapter does not authorize participation in the management of a labor organization or acting as a representative of a labor organization by a management official, a supervisor, or a confidential employee, or by any employee if the participation or activity would result in a conflict or apparent conflict of interest or would otherwise be incompatible with law or with the official duties of the employee.

(e) In the case of any labor organization which by omission or commission has willfully and intentionally called or participated in a strike, work stoppage or slowdown, or picketed in a manner which interfered with the operations of a government agency, or has condoned such activity, the Board shall, upon an appropriate finding it has made of such a violation—

(1) Revoke the recognition status of the labor organization; or

(2) Take any other appropriate disciplinary action.

(f) The General Counsel may charge a labor organization with violations of this section. The Board shall conduct proceedings with regard to such charge and may require a labor organization to take such actions as it deems necessary to carry out the policies of this section.

§ 28.124 Review of arbitration awards.

(a) *Filing an exception.* (1) Either party to arbitration, conducted pursuant to a grievance procedure under a collective bargaining agreement, may file with the Board an exception to the arbitrator's award rendered pursuant to the arbitration.

(2) The time limit for filing an exception to an arbitration award is 30 days from the service of the award on the filing party.

(3) An opposition to the exception may be filed by a party within 30 days after the service of the exception.

(4) A copy of the exception and any opposition shall be served on the other party.

(b) *Content of exception.* An exception must be a dated, self-contained document which sets forth in full:

(1) A statement of the grounds on which review is requested;

(2) Evidence or rulings bearing on the issues before the Board;

(3) Arguments in support of the stated grounds, together with specific reference to the pertinent documents and citations of authorities;

(4) A legible copy of the award of the arbitrator and legible copies of other pertinent documents; and

(5) The name and address of the arbitrator.

(c) *Grounds for review.* (1) The Board will review an arbitrator's award to which an exception has been filed to determine if the award is deficient—

(i) Because it is contrary to any law, rule or regulation; or

(ii) On other grounds similar to those applied by Federal courts in private sector labor-management relations.

(2) The Board will not consider an exception where:

(i) The award relates to an action based on unacceptable performance covered under 5 U.S.C. 4303;

(ii) The award relates to a removal, suspension for more than 14 days, reduction in grade, reduction in pay, or furlough of 30 days or less covered under 5 U.S.C. 7512; or

(iii) the exception is based on a GAO rule which was not introduced into the record submitted to the arbitrator.

(d) *Board decision.* The Board shall issue its decision and order taking such action and making such recommendations concerning the award as it considers necessary, consistent with applicable laws, rules, or regulations.

Subpart G—Corrective Action, Disciplinary and Stay Proceedings

§ 28.130 General authority.

The procedures in this subpart relate to the Board's functions "to consider, decide and order corrective or disciplinary action (as appropriate) in cases arising" from any area within the Board's jurisdiction.

§ 28.131 Corrective action proceedings.

(a) When information comes to the attention of the General Counsel suggesting that a prohibited personnel practice may have occurred, exists or is to be taken, the General Counsel shall investigate the matter to the extent necessary to determine whether there are reasonable grounds to believe that a prohibited personnel practice has occurred, exists or is to be taken.

(b) If the General Counsel terminates any investigation under this section which is not also the subject of a charge, the General Counsel shall prepare and transmit to any person on whose allegation the investigation was initiated, a written statement notifying the person of the termination of the investigation and the reasons therefore.

(c) If the General Counsel determines that there are reasonable grounds to believe that a prohibited personnel practice has occurred, exists or is to be taken which requires corrective action and which is not also the subject of a charge, the General Counsel shall report the determination together with any findings or recommendations to the GAO.

(d) If, after a reasonable period, GAO has not taken the corrective action recommended, the General Counsel may file a petition for review with the Board. Such petition for review shall be processed in accordance with §§ 28.19 through 28.25.

§ 28.132 Disciplinary proceedings.

(a) If the General Counsel determines after any investigation under 31 U.S.C. 752(b) that disciplinary action should be initiated against an employee, the General Counsel shall prepare a written complaint against the employee containing his or her determination, together with a statement of the supporting facts, and present the complaint and the statement to the employee and the Board in accordance with paragraphs (b) and (c) of this section.

(b) In the case of an employee in a confidential, policy making, policy-determining, or policy-advocating position appointed by the President, by and with the advice and consent of the Senate, the complaint and statement referred to in paragraph (a) of this section, with any response by the employee, shall be presented to the Congress for appropriate action in lieu of being presented under paragraph (d) of this section.

(c) Any employee against whom a complaint has been presented to the Board under paragraph (a) of this section is entitled to:

(1) A reasonable time to answer orally and in writing and to furnish affidavits and other documentary evidence in support of the answer;

(2) Be represented by an attorney or other representative;

(3) A hearing before the Board or a member designated by the Board;

(4) Have a transcript kept of any hearing under paragraph (c)(3) of this section; and

(5) A written decision and reasons therefor at the earliest practicable date, including a copy of a final decision ordering disciplinary action.

(d) A final order of the Board may order disciplinary action consisting of removal, reduction in grade, debarment from GAO employment for a period not to exceed 5 years, suspension, reprimand, or an assessment of civil penalty not to exceed $1,000.

(e) There may be no administrative appeal from an order of the Board under paragraph (d) of this section. An employee subject to a final decision ordering disciplinary action under this section may obtain judicial review of the order in the U.S. Court of Appeals for the Federal Circuit in accordance with 31 U.S.C. 755.

§ 28.133 Stay proceedings.

(a) The General counsel may request the issuance of an ex parte stay, not to exceed 30 days in duration, of any proposed personnel action that, in the General Counsel's judgment, may constitute a prohibited personnel practice. Any such request shall be in writing and shall specify, among other things, the nature of the action to be stayed and the basis for the General Counsel's belief that a prohibited personnel practice may be involved. The General Counsel shall serve a copy of the request on the GAO. Within three business days of its filing, the request shall be granted by the Board member designated by the Board Chair to entertain it unless, in the opinion of that member, the request either fails to satisfy the requirements of this paragraph or, on its face, conclusively establishes the absence of a prohibited personnel practice.

(b) The General Counsel may request either a further temporary stay or a permanent stay of the proposed personnel action. Such a request shall be filed and served so as to be received by the Board and the agency no less than 10 days before the expiration of any ex parte stay issued under paragraph (a) of this section. The agency's response to the request shall be filed and served so as to be received by the Board and the General Counsel no less than three days before the expiration of the ex parte stay issued under paragraph (a) of this section.

(c) A stay request under paragraph (b) of this section will be considered and decided by the Board member who issued the ex parte stay under paragraph (a) of this section, unless the Board Chair determines that it should be considered and decided by the Board en banc.

(d) Upon initial consideration of a stay request under paragraph (b) of this section, the Board or the designated member thereof may:

(1) grant or deny the requested stay, in whole or in part, on the basis of the written submissions of the respective parties without additional briefing, oral argument, or the receipt of any documentary evidence or testimony;

(2) require further briefing of the issues presented by the request and/or call for oral argument; or

(3) conduct a hearing at which documentary evidence and testimony is received. If necessary, the ex parte stay issued under paragraph (a) of this section may be extended sua sponte for a period not to exceed 30 days to enable the Board or the designated member thereof a reasonable opportunity to decide the matter.

(e) In acting upon a stay request under paragraph (b) of this section, the Board or the designated member thereof shall consider and balance such established equitable factors as:

(1) The likelihood that the personnel action sought to be stayed involves a prohibited personnel practice; and

(2) The nature and extent of the injury that the employee and the agency likely will suffer if the requested stay is or is not issued. If a further temporary stay is granted based on a claim that the General Counsel requires additional time to conclude an investigation of the employee's complaint, the duration of that further stay shall not exceed the amount of time necessary to complete the investigation in the exercise of a high degree of diligence.

(f) Any order issued by a member of the Board granting or denying, in whole or in part, a stay request under paragraph (b) shall be subject to review by the Board en banc on the filing and service of a notice of appeal, accompanied by a supporting brief, within 10 days of the service of that order. Responsive briefs shall be filed and served within 10 days of service of the appeal.

(g) A motion to vacate a stay order may be filed at any time. A stay order issued by the Board en banc may not be vacated by a single Board member.

Subpart H—Appeals by Members of the Senior Executive Service

§ 28.140 Personnel actions involving SES members.

Members of the GAO Senior Executive Service (SES) may appeal adverse actions relating to misconduct, malfeasance or similar action to the Board in accordance with Subpart B of this part. Members of the GAO SES who allege that they have been subjected to a personnel action that constitutes a prohibited personnel practice or prohibited discrimination may appeal to the Board in accordance with subpart B or subpart D of this part respectively.

§ 28.141 Performance based actions.

A career appointee removed from SES to a GAO position outside the SES for less than fully successful executive performance shall, upon notice of such removal, be entitled, upon request, to an informal hearing before a member of the Board designated by the Chair of the Board.

(a) At the informal hearing, the career appointee and/or a representative and the agency may appear and present documentary evidence and argument.

(b) The Board member will determine which, if any, witnesses will be allowed to testify. As a general rule, no cross-examination of witnesses will be allowed. The Board member will have discretion to allow cross-examination of witnesses in exceptional circumstances.

(c) The informal hearing shall not give the career appointee the right to initiate an action with the Board under another provision of these rules, nor need the removal action be delayed as a result of the granting of such hearing.

Subpart I—Ex Parte Communications

§ 28.145 Policy.

It is the policy of the Board to regulate strictly ex parte communications between members of the Board and their decision-making personnel and any interested party to a proceeding before the Board.

§ 28.146 Explanation and definitions.

(a) Ex parte communications are oral or written communications between decision-making personnel of the Board and an interested party to a proceeding without providing the other parties to the proceeding a chance to participate. Not all ex parte communications are prohibited, however, only those which involve the merits of the case or those which violate other rules requiring submissions to be in writing. Accordingly, interested parties may make inquiries about such matters as the status of a case, when it will be heard, and the method for transmitting evidence to the Board. Such communications should be directed to the Clerk of the Board. Parties may not inquire about such matters as what defense they should use or whether their evidence is adequate, make a submission orally which is required to be in writing, or otherwise inquire as to the merits of a pending case.

(b) In this subpart—

(1) "Interested party" includes:

(i) Any party, including the General Counsel of the Board, or representative

of a party involved in a proceeding before the Board;

(ii) Any person desiring to intervene in any proceeding before the Board; or

(iii) Any other person who might be affected by the outcome of a proceeding before the Board.

(2) "Decision-making personnel" means the Board, a panel of Board members, a Board member, an administrative judge, and/or an employee of the Board, who reasonably can be expected to participate in the decision-making process of the Board.

§ 28.147 Prohibited communications.

Ex parte communications concerning the merits of any matter before the Board for adjudication, or which would otherwise violate rules requiring written submissions, are prohibited from the time the interested party involved has knowledge that the matter may be considered by the Board until the Board has rendered a final decision on the case.

§ 28.148 Reporting of communications.

Any communication made in violation of this section shall be made part of the record in the proceeding and an opportunity for rebuttal allowed. If the communication was oral, a memorandum stating the substance of the discussion shall be placed in the record.

§ 28.149 Sanctions.

The following sanctions shall be available for violations of this Subpart:

(a) The Board, a panel of Board members, a Board member or an administrative judge, as necessary, may, in the interest of justice, require the offending party to show cause why his or her claim, interest, motion or petition should not be dismissed, denied or otherwise adversely affected.

(b) The Board, a panel of Board members, a Board member or an administrative judge, as necessary, may invoke such sanctions against any offending party as may be appropriate under the circumstances.

Subpart J—Statement of Policy or Guidance

§ 28.155 Statement of policy or guidance.

Upon petition by any person, or on its own motion, the Board may issue statements of policy or guidance. In determining whether to issue such a statement, the criteria to be considered by the Board will include, but not be limited to, the following:

(a) Whether the question presented can more appropriately be resolved by other means;

(b) Where other means are available, whether a Board statement would prevent the proliferation of cases;

(c) Whether the resolution of the question presented would have general applicability;

(d) Whether the question currently confronts the parties as part of their employee-management relationship;

(e) Whether the question is presented jointly by the parties involved; and

(f) Whether the issuance by the Board of a statement of policy or guidance would promote the purposes of the General Accounting Office Personnel Act.

Alan S. Rosenthal,

Chair, Personnel Appeals Board, General Accounting Office.

[FR Doc. 93–28652 Filed 11–22–93; 8:45 am]

BILLING CODE 1610–01–P

federal register

Tuesday
November 23, 1993

Part IV

Department of the Interior

Bureau of Indian Affairs

Petition for Acknowledgement of Existence as Indian Tribe; Wintu Tribe of Northern California; Notice

DEPARTMENT OF THE INTERIOR

Bureau of Indian Affairs

Receipt of Petition for Federal Acknowledgment of Existence as an Indian Tribe

AGENCY: Bureau of Indian Affairs, Interior.

ACTION: Notice.

SUMMARY: This is published in the exercise of authority delegated by the Secretary of the Interior to the Assistant Secretary—Indian Affairs by 209 DM 8.

Pursuant to 25 CFR 83.8(a) (formerly 25 CFR 54.8(a)) notice is hereby given that the Wintu Tribe of Northern California, c/o Caleen Sisk-Franco, 1226 Jackson Street, Chico, California 95928, has filed a petition for acknowledgment by the Secretary of the Interior that the group exists as an Indian tribe. The petition was received by the Bureau of Indian Affairs (BIA) on August 25, 1993, and was signed by members of the group's governing body.

This is a notice of receipt of petition and does not constitute notice that the petition is under active consideration. Notice of active consideration will be sent by mail to the petitioner and other interested parties at the appropriate time.

Under section 83.8(d) (formerly 54.8(d)) of the Federal regulations, interested parties may submit factual and/or legal arguments in support of or in opposition to the group's petition. Any information submitted will be made available on the same basis as other information in the BIA's files. Such submissions will be provided to the petitioner upon receipt by the BIA. The petitioner will be provided an opportunity to respond to such submissions prior to a final determination regarding the petitioner's status.

The petition may be examined, by appointment, in the Department of the Interior, Bureau of Indian Affairs, Branch of Acknowledgment and Research, room 1362–MIB, 1849 C Street, NW., Washington, DC 20240, Phone: (202) 208–3592.

FOR FURTHER INFORMATION CONTACT: Holly Reckord, (202) 208–3592.

Dated: September 27, 1993.

Ada E. Deer,

Assistant Secretary—Indian Affairs

[FR Doc. 93–28646 Filed 11–22–93; 8:45 am]

BILLING CODE 4310–02–P

federal register

Tuesday
November 23, 1993

Part V

Department of Agriculture

Food Safety and Inspection Service

9 CFR Part 306, et al.
Prior Labeling Approval System;
Proposed Rule

DEPARTMENT OF AGRICULTURE

Food Safety and Inspection Service

9 CFR Parts 306, 317, 320, 327, and 381

[Docket No. 92-012P]

RIN 0583-AB50

Prior Labeling Approval System

AGENCY: Food Safety and Inspection Service, USDA.

ACTION: Proposed rule.

SUMMARY: The Food Safety and Inspection Service (FSIS) is proposing to amend the Federal meat and poultry products inspection regulations by expanding the types of labeling currently authorized for use on meat and poultry products by official establishments in the United States and foreign establishments certified under foreign inspection systems which would be generically approved. FSIS is also requesting comment on an alternative option where all labeling for meat and poultry products would be generically approved. This proposal would eliminate unnecessary duplication in the labeling approval system, and contribute to President Clinton's initiatives for greater efficiency in government services.

DATES: Comments must be received on or before January 24, 1994.

ADDRESSES: Written comments to: Policy Office, Attn: Diane Moore, FSIS Hearing Clerk, room 3171, South Agriculture Building, Food Safety and Inspection Service, U.S. Department of Agriculture, Washington, DC 20250. Oral comments as provided by the Poultry Products Inspection Act should be directed to Ms. Cheryl Wade, (202) 254-2590. (See also "Comments" under SUPPLEMENTARY INFORMATION.)

FOR FURTHER INFORMATION CONTACT: Ms. Cheryl Wade, Acting Director, Food Labeling Division, Regulatory Programs, Food Safety and Inspection Service, U.S. Department of Agriculture, Washington, DC 20250, Area Code (202) 254-2590.

SUPPLEMENTARY INFORMATION:

Executive Order 12866

The proposed rule has been reviewed under Executive Order 12866. The proposed rule would eliminate an estimated $4 million in direct label application costs and reduce the paperwork burdens of operators of all official establishments in the United States and establishments in foreign countries certified by responsible officials of foreign inspection systems by reducing the types of labeling that would have to be submitted for prior review and approval by FSIS. Such foreign establishments are certified by responsible officials of foreign meat and poultry inspection systems, to the Department, in accordance with parts 327 and 381, subpart T, of the Federal meat and poultry products inspection regulations as fully complying with requirements at least equal to those imposed on domestic products and establishments. Such foreign establishments are then eligible to have their meat and poultry products imported into the United States, unless the Administrator terminates their eligibility to import products in accordance with parts 327 and 381, subpart T, of the Federal meat and poultry products inspection regulations. The proposed rule would also reduce market inefficiencies caused by delays in new product introduction attributable to the labeling application and review process.

Executive Order 12778

This proposed rule has been reviewed under Executive Order 12778, Civil Justice Reform. States and local jurisdictions are preempted under the Federal Meat Inspection Act (FMIA) and the Poultry Products Inspection Act (PPIA) from imposing any marking, labeling, packaging, or ingredient requirements on federally inspected meat and poultry products that are in addition to, or different than, those imposed under the FMIA or PPIA. States and local jurisdictions may, however, exercise concurrent jurisdiction over meat and poultry products that are outside official establishments for the purpose of preventing the distribution of meat and poultry products that are misbranded or adulterated under the FMIA or PPIA, or, in the case of imported articles, which are not at such an establishment, after their entry into the United States. Under the FMIA and PPIA, States that maintain meat and poultry inspection programs must impose requirements that are at least equal to those required under the FMIA and PPIA. The States may, however, impose more stringent requirements on such State inspected products and establishments.

No retroactive effect will be given to this proposed rule. The administrative procedures specified in 9 CFR 306.5 and 381.35 must be exhausted prior to any judicial challenge of the application of the provisions of this rule, if the challenge involves any decision of an inspector relating to inspection services provided under the FMIA or PPIA. The administrative procedures specified in 9 CFR parts 335 and 381, subpart W, must be exhausted prior to any judicial challenge of the application of the provision of this rule with respect to labeling decisions.

Effect on Small Entities

The Administrator, FSIS, has made an initial determination that this proposed rule would not have a significant economic impact on a substantial number of small entities. This proposal would impact the small businesses referred to a label expediters because the number of labels requiring the existing expediting service would decrease. The initial determination is based on a finding that there is not a substantial number of expediters. The Agency also believes that the economic impact may not be significant if the existing label expeditors are able to modify the services they offer and provide consulting services to their existing clients. The proposed rule would also provide a positive, but not significant impact, on a large number of small meat and poultry processors and importers.

Reducing direct labeling application costs does not necessarily reduce the need for obtaining outside advice on how best to comply with labeling rules and regulations. FSIS is interested in receiving comments on the potential impact of this proposed rule on labeling expediters, domestic and foreign meat and poultry processors, and importers.

Paperwork Requirements

This proposal would require meat and poultry official establishments and foreign establishments certified by responsible officials of foreign meat and poultry inspection systems to maintain certain records supporting the use of labeling applied to meat and poultry products, and to make such records available to any duly authorized representative of the Secretary upon request. This proposal would expand the types of generically approved labeling currently authorized for use by official establishments and foreign establishments without being required to be submitted for approval by FSIS in Washington or in the field. The proposal would also require official establishments and establishments certified under foreign inspection systems to submit to FSIS for approval only sketch labeling, thus eliminating for such establishments submission to FSIS of final labeling, with the exception of temporary approvals.

FSIS is proposing that official establishments and establishments certified by responsible officials of foreign inspection systems maintain a copy of all labeling used on product,

along with the product formulation and processing procedures. Such records would be required to be made available to any duly authorized representative of the Secretary. FSIS believes that if a question arises regarding a labeling issue, a copy of the labeling in question, along with the product formulation and processing procedures, should be made available to the inspector or other authorized representative of the Secretary. The Agency is also proposing to conduct random sampling of generically approved labeling from the records maintained by official establishments in order to monitor compliance with labeling requirements. Thus, such recordkeeping of labeling would be necessary to accommodate that monitoring process.

The paperwork requirements contained in this proposal have been submitted to the Office of Management and Budget for approval under the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*).

Alternative Option Considered

In developing this proposal, FSIS also considered the alternative of proposing a system where all labeling for domestic and imported products would be generically approved.

Under this alternative, there would not be any labeling review and approval conducted by program employees, either at headquarters or in the field. Establishments would be authorized to design, develop, print and apply labeling without any submission to FSIS, provided the labeling complies with existing labeling regulations. As with generically approved labeling under the proposed rule, establishments would be required to maintain records for all labeling. These records would include a copy of the labeling used on the product and a record of the product formulation and processing procedure. In addition, similar to the proposed rule, an all-generic system would include an enhanced sampling program to assure that labeling is accurate and not misleading. It is envisioned that this sampling program would supplement, but not replace, the existing inplant inspection task that directs inspectors of official establishments and analogous personnel of certified foreign establishments to check a sample of labeling to determine if the labeling is correct and used as intended. The Agency intends to complete an assessment of existing and planned sampling in conjunction with development of the final rule.

Both the proposed rule and the alternative of expanding generic approvals to cover all labeling were identified in an Advance Notice of Proposed Rulemaking (ANPR) published on March 25, 1992. The Department recognizes that both options identified in the ANPR represent a change in how firms would conduct new product development and new product introduction. Because these decisions are so integrally related to business profits and financial viability, it is understandable that this rulemaking has raised concerns. There are certainly unknowns and uncertainties raised by the alternative of total elimination of the headquarter's labeling review function. As mentioned above, the Agency is seeking comments to further evaluate the total generic option. To facilitate these comments, the Agency has summarized what it views as the three primary concerns associated with the second option of the ANPR. These are:

1. The headquarters' review function in the present system identifies and corrects problems with many labeling applications. To maintain the current level of accuracy, the FSIS review function will have to be replaced. Firms will have the option of expanding their internal knowledge of labeling rules and regulations or seeking outside advice from experts or consultants. FSIS is seeking specific comments that address the question of additional resources required by official establishments. It may be that a body of central expertise is most efficient, whether or not that function resides within FSIS.

2. As mentioned above, inspectors in official establishments and analogous personnel for foreign establishments currently examine labeling to determine if it is correct and used as intended.

Occasionally, product is retained if the inspector determines that the labeling is false or misleading. If the accuracy of labeling is maintained, the Agency foresees no reason for the frequency of such actions to change. Under either option, the Agency already has procedures for appealing decisions by Program employees, including the denial or withdrawal of the use of labeling on meat and poultry products. The type of problem frequently identified through inspection is the presence of an ingredient not identified in the ingredient list or the absence of an ingredient that is listed. There is no reason to believe that Agency review of labeling (the current system) reduces the frequency of this type of labeling error.

3. Some labeling is developed in conjunction with an entirely new product or new process, and may use new processing techniques and/or new equipment not previously approved. Under the current system, firms have the option of obtaining headquarter's approval of labeling and equipment before they invest in new equipment or make plant modifications. There may be some concern that without headquarter's review and approval of such labeling, firms would be more reluctant to take risks. A total generic approval system would not necessarily reduce all delays in new product introduction currently attributable to the labeling application and review process. Under such a system, the Agency would not be reviewing labeling associated with new products or processes. It would, however, be unrealistic to presume that the Agency could entirely remove itself from the function of providing policy advice and guidance on the acceptability of new products or ingredients. An almost identical concern is the specter of having labeling rejected after it has been used extensively and captured a share of the market. As with new products or processes, the removal of the review function does not mean that firms will be operating in a policy vacuum.

Comments

Interested persons are invited to submit comments concerning this proposal. Written comments should be sent to the Policy Office and refer to Docket No. 92–012P. Any person desiring an opportunity for an oral presentation of views, as provided by the Poultry Products Inspection Act, should make such request to Ms. Cheryl Wade so that arrangements can be made for such views to be presented. A transcript will be made of all views orally presented. All comments submitted in response to this proposal will be available for public inspection in the Policy Office from 9 a.m. to 12:30 p.m. and from 1:30 p.m. to 4 p.m., Monday through Friday.

Background

Introduction

The Federal Meat Inspection Act (FMIA) (21 U.S.C. 601 *et seq.*) and the Poultry Products Inspections Act (PPIA) (21 U.S.C. 451 *et seq.*) direct the Secretary of Agriculture to maintain meat and poultry inspection programs designed to assure consumers that meat and poultry products distributed to them (including imports) are wholesome, not adulterated, and properly marked, labeled, and packaged.

Section 2 of the FMIA (21 U.S.C. 602) and section 2 of the PPIA (21 U.S.C. 451) state that unwholesome, adulterated, or misbranded meat or meat food products and poultry products are injurious to the public welfare, destroy markets for wholesome, not adulterated,

and properly marked, labeled, and packaged products, and result in sundry losses to producers and processors of meat and poultry products, as well as injury to consumers. Therefore, Congress has granted the Secretary broad authority to protect consumers' health and welfare. Section 7(d) of the FMIA (21 U.S.C. 607(d)) states: "No article subject to this title shall be sold or offered for sale by any person, firm, or corporation, in commerce, under any name or other marking or labeling which is false or misleading, or in any container of a misleading form or size, but established trade names and other marking and labeling and containers which are not false or misleading and which are approved by the Secretary are permitted." The PPIA contains similar language in section 8(c) (21 U.S.C. 457(c)).

Under the latter provisions, the Secretary of Agriculture or his or her representative has the responsibility to approve all labels or other labeling to be used on Federally inspected and imported products prior to the distribution of such products from establishments that distribute such products in interstate or foreign commerce. Without approved labeling, products may not be sold or offered for sale or otherwise distributed in commerce. The term "labeling", as defined in section 1(p) of the FMIA and section 4(s) of the PPIA (21 U.S.C. 601(p) and 453(s), respectively), means all labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article.

The aforementioned provisions also apply to establishments that operate solely within designated States. A State is designated if it does not have or is not effectively enforcing with respect to establishments within its jurisdiction at which livestock or poultry are slaughtered, or their carcasses, or products thereof, are prepared for use as human food solely for distribution within such State, requirements at least equal to titles I and IV of the FMIA and specified sections of the PPIA as applicable. Once a State is designated, the inspection requirements of the FMIA and PPIA apply to establishments that slaughter livestock and poultry and/or prepare or process meat and/or poultry products therefrom, solely for distribution within the State.

Section 1(m)(8) of the FMIA (21 U.S.C. 601(m)(8)) and section 4(g)(8) of the PPIA (21 U.S.C. 453(g)(8)) provide that any carcass, part thereof, meat or meat food product or any poultry product is adulterated "* * * if any valuable constituent has been in whole or in part omitted or abstracted therefrom; or if any substance has been substituted, wholly or in part therefor; or if damage or inferiority has been concealed in any manner; or if any substance has been added thereto or mixed or packed therewith so as to increase its bulk or weight, or reduce its quality or strength, or make it appear better or of greater value than it is * * *." Furthermore, section 1(n)(1) of the FMIA (21 U.S.C. 601(n)(1)) and section 4(h)(1) of the PPIA (21 U.S.C. 453(h)(1)) prescribe that any carcass, part thereof, meat or meat food product or poultry product is considered misbranded if its labeling is false or misleading in any particular.

In order to prevent product adulteration and misbranding, the FMIA and PPIA further authorize the Secretary to prescribe, whenever he or she determines such action is necessary for the protection of the public, (1) the styles and sizes of type to be used with respect to material required to be incorporated in labeling to avoid false or misleading labeling, and (2) definitions and standards of identity or composition for meat and poultry products (section 7(c) of the FMIA, 21 U.S.C. 607(c), and section 8(b) of the PPIA, 21 U.S.C. 457(b)).

Current Regulations

The labeling provisions of the meat and poultry products inspection regulations specify the required features of meat and poultry product labels for immediate containers of domestic product (9 CFR part 317 and 9 CFR part 381, subpart N) and for imported product (9 CFR part 327 and 9 CFR part 381, subpart T). These include: (1) The standardized, common or usual, or descriptive name of the product; (2) an ingredients statement containing the common or usual name of each ingredient listed in descending order of predominance; (3) the name and place of business of the manufacturer, packer, or distributor; (4) an accurate statement of the net quantity of contents; (5) the inspection legend; and (6) special handling instructions if product is perishable; i.e., "Keep Frozen" and "Keep Refrigerated." These essential labeling features must be prominently and informatively displayed on the principal display panel or the information panel of the product label.

The regulations contain other provisions to ensure that no statement, word, picture, design, or device which is false or misleading in any particular or conveys any false impression or gives any false indication of origin, identity, or quality, shall appear in any marking or other labeling (9 CFR 317.8 and 381.129). For example, for meat products terms having geographic significance with reference to a locality other than that in which the product is prepared may appear on the label only when qualified by the word "style", "type", or "brand", as the case may be, and accompanied with a prominent qualifying statement identifying the country, State, territory, or locality in which the product is prepared (9 CFR 317.8(b)(1)). Further, coverings for meat or meat products shall not be of such color, design, or kind as to be misleading with respect to color, quality, or kind of product (9 CFR 317.8(b)(5)).

Any marking or labeling which is determined to be false or misleading within the meaning of the FMIA or the PPIA and the regulations promulgated thereunder causes the article to which it relates to be misbranded, and, pursuant to the authority contained in section 7(e) of the FMIA (21 U.S.C. 607(e)) and section 8(d) of the PPIA (21 U.S.C. 457(d)), and §§ 335.12 and 381.233 of the Federal meat and poultry products inspection regulations (9 CFR 335.12 and 381.233), the Administrator, FSIS, may withhold the use of such marking or labeling.

In addition to providing substantive labeling requirements, the Federal meat and poultry products inspection regulations provide specific information regarding permitted and nonpermitted uses of various substances (9 CFR part 318 and part 381, subpart 0). These provisions prohibit the use of any food additive, color additive, pesticide chemical, or other added poisonous or deleterious substance, or any other substance in or on meat and poultry products that would cause such articles to be adulterated or misbranded within the meaning of the FMIA and PPIA. These provisions are designed to ensure, among other things, that ingredients aimed at improving physical qualities of a product, such as flavor, color, and shelf-life, meet a specific justifiable need in the product and do not promote deception as to product freshness, quality, weight, or size, or otherwise cause the product to be adulterated or misbranded.

The Federal meat and poultry products inspection regulations also prescribe definitions and standards of identity or composition for certain meat and poultry products (9 CFR part 319 and part 381, subpart P). Standards of composition identify the minimum amount of meat and/or poultry required in a product's recipe. For example, the standard of composition for "Chicken a la King" requires that, if a product bears this name on its label, at least 20

percent cooked deboned poultry meat must be used in the recipe (9 CFR 381.167).

Standards of identity set specific product requirements for a product's makeup. These standards often specify (1) the kind and minimum amount of meat and/or poultry; (2) the maximum amount of nonmeat ingredients, such as fat or moisture; and (3) any other ingredients allowed or expected in the final product.

Meat and poultry product standards provide a simple and direct means by which consumers can learn what to expect from a product if it is labeled with a particular name. Thus, these requirements help to ensure that consumers' expectations are met.

Current Prior Label Approval System

In order to assure that meat and poultry products comply with the FMIA and PPIA and the regulations promulgated thereunder, FSIS conducts a prior approval program for labels and other labeling as specified in 9 CFR 317.4, 317.5, 327.14, 327.15, 381.132, 381.134, and 381.205 to be used on federally inspected meat and poultry products and imported products. This program is administered by the Food Labeling Division (FLD), Regulatory Programs, FSIS, in Washington, DC.

To obtain labeling approval, domestic meat and poultry processors and certified foreign establishments, or their representatives, must submit final labels and other final labeling, except under certain conditions. Meat and poultry processors and certified foreign meat establishments may submit sketch labeling (a printer's proof or other version which clearly shows all required labeling features, size, location, and indication of final color), accompanied by FSIS Form 7234, "Application for Approval of Labels, Marking or Device," to FLD for review. Certified foreign poultry establishments are required to submit sketch and finished (final) labels of immediate containers for review and approval. The labeling application and sketch or final printed labeling to be used on domestic meat and poultry products and on imported meat products must be submitted to FLD in triplicate. Certified foreign poultry establishments must submit two copies of sketch and four copies of final labels to FLD. In addition to the required information, any special claims the processor intends to make (e.g., quality claims or nutrient content claims) must also be included on the labeling. The labeling application must contain the processing procedures and handling information, including the following as indicated on the form:

1. Product name; i.e., the standardized, common or usual, or descriptive name of the product;

2. Formulation information; i.e., listing by percentage or actual amount of ingredients in descending order of predominance, and method of preparation;

3. Firm name and address;

4. How the labeling is to be used; i.e., consumer size, institutional capacity, or shipping container;

5. Size and type of container, such as wrapper, casing, or carton; and

6. Size of the principal display panel.

All such information is reviewed by an FSIS label review specialist who is responsible for assuring that the labeling complies with all Federal regulations and labeling policies.

In 1983, the Agency promulgated regulations which granted limited labeling approval authority to the inspector-in-charge (IIC) of official establishments and established limited types of generically approved labeling for official establishments (48 FR 11410). This rulemaking did not establish analogous provisions for certified foreign establishments. This rulemaking was intended to reduce the number of labels and other labeling reviewed and processed by FLD, thereby improving the efficiency of the labeling approval system by expediting the process for specific types of labeling and reducing the paperwork burden on official establishments. As a result of these regulations, the IIC has authority (9 CFR 317.4(e) and 381.132(c)) to approve the following types of labeling provided certain requirements are satisfied:

1. Final labeling of labeling already approved in sketch or proof form by FLD and the final labeling is prepared without modification or with only minor modification as follows:

a. Brand name changes, provided there are no design changes, the brand name does not use a term that connotes quality or other product characteristics, the brand name has no geographic significance and the brand name does not affect the name of the product;

b. The deletion of the word "new" on new product labeling;

c. The addition, deletion, or amendment of handling instructions, provided that the change is consistent with § 317.2 or § 381.125;

d. Changes reflecting a change in the quantity of an ingredient shown in the formula without a change in the order of predominance shown on the label, provided the change in quantity of ingredients complies with any minimum or maximum limits for the use of such ingredients prescribed in parts 318 and 319 or § 381.147;

e. Changes in the color of the labeling, provided that the IIC is satisfied that sufficient contrast and legibility remain;

f. A change in the product vignette, provided the change does not affect mandatory labeling information; or

g. The addition, deletion, or substitution of the official USDA grade shield on labeling for poultry products;

2. Labeling for single-ingredient products (such as beef steaks, or lamb chops, or chicken or turkey thighs) which do not contain quality claims (such as "blue ribbon" or "choice"), negative claims (such as "no sugar added"), geographical claims, nutritional claims, guarantees, or foreign language;

3. Labeling for containers of meat and meat food products and poultry products sold under contract specifications to Federal Government agencies, when such product is not offered for sale to the general public, provided the contract specifications include specific requirements with respect to labeling, and are made available to the IIC;

4. Labeling for shipping containers which contain fully labeled immediate containers, provided such labeling for poultry products comply with § 381.127;

5. Labeling for products not intended for human food, provided they comply with part 325 and § 381.152(c), and labels for poultry heads and feet for export for processing as human food if they comply with § 381.190(b);

b. Inspection legends, which comply with parts 312 and 316 and with subpart M of part 381;

7. Meat carcass ink brands, and meat food product ink and burning brands, which comply with parts 312 and 316; and

8. Inserts, tags, liners, pasters, and like devices containing printed or graphic matter and for use on, or to be placed within containers, and coverings of products, provided such devices contain no reference to product and bear no misleading feature.

The regulations also specify limited types of generically approved labeling; that is, certain modified labeling authorized for use by the establishment without submission for approval to FSIS, provided such labeling was previously approved by FLD and the labeling shows all mandatory information in a sufficiently prominent manner and is not otherwise false or misleading in any particular (9 CFR 317.5 (a) and (b) and 381.134 (a) and (b)). The IIC is also currently authorized to approve these types of labeling (9

CFR 317.4(e)(3)(i) and 381.132(c)(3)(i)). Generically approved labeling is labeling which contains one or more of the following modifications:

1. All features of the labeling are proportionately enlarged or reduced, provided all minimum size requirements specified in applicable regulations are met and the labeling is legible;

2. There is substitution of such abbreviations as "lb." for "pound", or "oz." for "ounce", or the word "pound" or "ounce" is substituted for the abbreviation;

3. A master or stock label has been approved from which the name and address of the distributor are omitted and such name and address are applied before being used (in such case, the words "prepared for" or similar statement must be shown together with the blank space reserved for the insertion of the name and address when such labels are offered for approval);

4. During holiday seasons, wrappers or other covers bearing floral or foliage designs or illustrations of rabbits, chicks, fireworks, or other emblematic holiday designs are used with approved labeling (the use of such designs will not make necessary the application of labeling not otherwise required);

5. There is a change in the language or the arrangement of directions pertaining to the opening of containers or the serving of the product;

6. The addition, deletion, or amendment of a coupon, a cents-off statement, cooking instructions, packer product code information, or UPC product code information;

7. Any change in the name or address of the packer, manufacturer, or distributor that appears in the signature line;

8. Any change in the net weight, provided the size of net weight statement complies with § 317.2 or § 381.121 of the regulations;

9. The addition, deletion, or amendment of recipe suggestions for the product;

10. Any change in punctuation;

11. Newly assigned or revised establishment numbers for a particular establishment for which use of the labeling has been approved by FLD or the IIC assigned to that establishment;

12. The addition or deletion of open dating information;

13. A change in the type of packaging material on which the label is printed; or

14. The addition of safe handling instructions as required by § 317.2 or § 381.125.

Under current regulations, official establishments are not required to submit labeling, that comes within the categories of labeling the IIC can approve, to the IIC for approval, but rather have the option of submitting the labeling to FLD for approval. Further, under the regulations, official establishments may submit labeling that comes within the generically approved category, at their option, to FSIS for approval.

Currently, official establishments may submit sketch labeling but must submit final labeling to FLD for approval, except as discussed above. When the official establishment prints final labeling based on a previously approved sketch, the final labeling, along with a labeling application, must still be processed and approved by either the IIC or FLD, depending on the modification made to the final labeling. Although the IIC has the authority to approve some of these final labeling, it is not mandatory and, consequently, many official establishments have continued to submit them to FLD for approval.

The Agency believed that the 1983 provisions would decrease the number of labels and other labeling submitted to FLD, and reduce the industry's burden by eliminating the need for FSIS approval of labeling with certain modifications. However, these provisions have not alleviated the burden on industry, nor have they significantly reduced the number of labels and other labeling being submitted to FLD. During the development of the 1983 rule, FSIS estimated the number of labels and other labeling reviewed by FLD at approximately 130,000. During fiscal year 1991, FLD processed approximately 210,000 labels—87,500 final labels and 60,000 sketch labels were reviewed and approved, 20,000 labels were reviewed but not approved, and about 43,000 IIC-approved labels were received for auditing. No records are maintained on numbers of temporary approvals, generically approved labels, or labeling inserts.

The continuing increase in the numbers of labels and other labeling submitted to FLD and limited Agency resources led to an Agency assessment of the prior label approval system in 1990. In exploring options for an improved labeling approval system, the Agency decided to institute a plan to automate the labeling review process and to revise internal procedures.

Modernizing the Labeling Approval System

FSIS plans to modernize its procedure for labeling approval by implementing a new system to be called the Label Analysis, Tracking, and Information System (LATIS). This system will include information on policy, rules, technical references, nutrition information, and previously submitted applications. FSIS labeling review specialists will be able to apply the information to analyze the components of a proposed label and other labeling and to electronically route the labeling through the necessary steps towards approval.

The purpose of LATIS, which will be phased into operation over several years, will be to improve the efficiency, uniformity, and accuracy of the labeling review procedure. The new labeling review procedures will replace the current manual system that evolved to meet the needs of a simpler, smaller food industry. Internal assessments and a report by the USDA Inspector General in 1990 recommended changes in the current labeling approval system to improve efficiency and to address projected increases in both volume and complexity of labeling applications. FSIS believes that an automated labeling review procedure is necessary to keep pace with advancing technology, changing consumer expectations, and emerging health concerns.

As the first step, FSIS is implementing a label tracking system, electronic access to technical references, and calculation assistance for evaluating nutrition information on labels. In addition, the Agency is designing a new application form that will allow electronic data entry and automatic calculations of restricted ingredients allowances. The automated system will provide FSIS label reviewers with the capability of electronic analysis, tracking, and information retrieval.

Discussion of Comments

On March 25, 1992, FSIS published an Advance Notice of Proposed Rulemaking (ANPR) (57 FR 10300) on the Agency's prior labeling approval system. The ANPR presented the following two options for making additional changes to the current prior label approval system: (1) Revise the current system by significantly reducing the scope of review, through expanding the categories of generically approved labeling and replace the current general requirement of FSIS approval of sketch and final labeling with one for sketch labeling only; and (2) replace the current system with a system in which all labeling would be generically approved and used without prior submission to FSIS.

FSIS sought comments on these two options and welcomed comments on other options. FSIS also sought

comments on the role of the IIC with regard to review or enforcement of labeling, and on whether generic approval should be provided for labeling that includes geographical, quality, health, nutrient content, or negative claims, or guarantees.

FSIS received 110 comments in response to the ANPR. Sixty-one comments were submitted by meat and poultry manufacturers, while 18 were received from consumers, 9 from trade associations, 2 from food retailers, 7 from professional organizations, 9 from label expediters, 2 from food service organizations, 1 from a Federal employee, and 1 from an importer/exporter.

The majority of the commenters agreed that expanding the generic categories and approving sketch labeling was the preferable system to adopt (option 1). The comments favoring this option raised several other issues in support of the option. Several commenters supported an all generic approval system (option 2). Only one commenter addressed the issue regarding generic approval for labeling that included claims. One consumer group stated that generically approved labeling with claims should be subject to prior approval. Other issues raised by the commenters and the Agency's response to each issue are as follows:

1. Sketch Approval and Voluntary Final Approval

Most commenters strongly agreed that submission of sketches for approval should replace the general requirement that final labeling be submitted for current approval and offered various modifications to this type of revision consistent in part with Option 1 in the ANPR. These modifications were to have all sketches approved by FLD and to include voluntary final approvals as part of the approval system. One commenter, however, suggested that sketch approval by FLD be optional. Over 50 percent of the comments in support of sketch approval also supported FLD's approving final labeling if submitted to it on a voluntary basis. Commenters believed that offering voluntary approval of final labeling would provide additional assurance that the labeling met all regulatory requirements.

FSIS is proposing a system of submission of sketch labeling to FLD, for approval, except for certain categories of generically approved labeling, with no requirement or allowance for submission of final labeling to FLD or the field for approval, except for temporary approved labeling (see proposed §§ 317.4(g), 381.132(g)). FSIS believes it is an unnecessary burden on industry and FSIS to require the submission of final labeling when the sketch has been previously approved. The Agency believes certain types of modifications to sketch labeling can be made by official establishments and certified foreign establishments and need not be required to be submitted for review.

In addition, one commenter suggested that FSIS require sketch approval for products with a standard of identity or composition rather than including this category under generic labeling. The Agency believes that approval of sketches for standardized product labeling is unnecessary because such labeling would pose little, if any, risk of misbranding since the regulatory standards specify the product name to be used on the labeling and the permitted ingredients.

2. Generic Approvals

Although the majority of commenters strongly supported option 1, which expands the category of generically approved labeling, several of those commenters believed that the generically approved category should be expanded even further. One commenter suggested that generic approvals be expanded to include sketch approval.

The Flavor and Extract Manufacturers Association supported option 2 as it applied to flavors. Flavors which are amenable to the Acts are subject to Prior Label Approval. FSIS has found these labels to be complex labels that require a high level of technical review. This is to assure that all reactions and resulting proteinaceous materials are properly identified in the ingredient statement. FSIS's regulations do not provide labeling instructions on these types of products. For this reason, FSIS believes this labeling should be subject to prior approval.

The commenter also requested elimination of FSIS's review of flavors by the Proprietary Mix Committee. This FSIS committee provides informal advice on labeling of nonamenable flavoring and batter and breading mixes, which is a voluntary service. FSIS believes the issue of eliminating the review by the Proprietary Mix Committee falls outside the scope of this rulemaking; therefore, the Agency will not address it in this rule.

While FSIS acknowledges that certain portions of the industry desire to further expand the category of generically approved labeling, the Agency is reluctant to expand the category any further until it can demonstrate that this labeling procedure will continue to provide the public with labeling that is accurate and not misleading.

3. Temporary Approval

Over 25 percent of the comments raised the issue of temporary approvals. The absence of a discussion in the ANPR led readers to believe that there may not be any provision for temporary approvals. Although FSIS is proposing that it would not require approval of final labeling, the Agency would continue to receive requests from establishments for temporary use of a final label for a period not to exceed 180 days, unless approved beyond 180 days, as further discussed under the "Proposed Rule" section of this document.

4. Approval of Labels for Imported Products

Over 10 percent of the commenters suggested that a revised labeling approval system provide sketch and final approval for foreign labels or labeling. FSIS believes these comments were referring to imported products. The Federal meat and poultry products inspection regulations identify those foreign countries which maintain meat and poultry inspection systems at least equal to the inspection systems of the United States, and which have been determined by FSIS to be eligible for importation of meat and poultry products into the United States (9 CFR 327.2 and 381.196). Only those establishments located in an approved foreign country and certified, as complying with "at least equal to" requirements, to FSIS by a responsible official of the approved foreign meat or poultry inspection system are eligible to have their meat or poultry products imported into the United States. Labeling for such products entering this country must meet to all USDA requirements. Therefore, FSIS believes all labeling for imported products should be under the same labeling review and approval process as administered for domestic products.

5. Role of the IIC

Commenters had varying opinions on the role of the IIC. The majority of commenters responding to this issue recommended that the IIC not have the authority to approve or disapprove labels or labeling and be prohibited from holding the shipment of product based on labeling issues unless there is a health and safety question.

This proposal would alleviate the burden of labeling approval from the IIC inspection activities. FSIS believes that product should be withheld from distribution in interstate or foreign

commerce or within "designated States" if the labeling is misbranded or may present a health, safety, or dietary concern to the consumer.

Section 7(e) of the FMIA (21 U.S.C. 607(e)) and section 8(d) of the PPIA (21 U.S.C. 457(d)) provide the Secretary with the authority to withhold the use of any marking, labeling, or container in use or proposed for use with respect to any article subject to the Acts if there is reason to believe that the marking or labeling or size or form of the container is false or misleading in any particular. This is further prescribed in §§ 335.12 and 381.233 of the Federal meat and poultry inspection regulations (9 CFR 335.12 and 381.233).

Several other commenters thought that the IIC should approve all labeling that is not approved in Washington. Still other commenters contended that the IIC's role should be increased to include more minor label changes and temporary approvals. In an effort to reduce the burden placed on FSIS inspectors, FSIS is proposing to expand the generic labeling categories, thereby allowing more time for inspectors to perform other inspection duties. The IIC, however, would retain the authority to approve meat carcass ink brands and meat food product ink and burning brands.

6. Labeling Appeals Process

Ten comments addressed the issue of establishing a process for labeling appeals when an inspector withholds the use of a labeling when there is reason to believe that it is false or misleading. However, none was specific as to how the process should be set up.

Under 9 CFR 306.5, 327.24, 381.35, and 381.202(d), appeals may be made on any decision made by an inspector, IIC, or other Program employee, except for the denial of a labeling application by the inspector or the IIC. Since the proposed rule would eliminate the IIC's authority to approve labeling applications, the exception to the appeals procedure would be removed.

Furthermore, 9 CFR 335.12 and 381.233 provide that when the Administrator determines that any marking or labeling or size or form of any container in use or proposed for use with respect to any meat or poultry product is false or misleading in any particular, he shall notify, in writing, the person, firm, or corporation using or proposing to use such marking, labeling, or container that such use shall be withheld unless the marking, labeling, or container is modified in such a manner as the Administrator may prescribe so that it would not be false or misleading. The person, firm, or corporation is provided an opportunity to respond to the Administrator's notification and a right to request a hearing regarding the merits or validity of the withholding action.

7. Maintain Current System

Commenters suggested as an option for consideration that the current prior labeling approval system be maintained. FSIS believes that the current prior approval system involves several hindrances to economic growth. Producers of meat and poultry products face direct labeling application costs. In addition, delays in the application process slow marketplace introduction of new products, imposing added costs on manufacturers. Therefore, FSIS is proposing changes to the current prior labeling approval system.

8. Preemption

One commenter raised the concern regarding generic approvals jeopardizing Federal preemption provisions. FSIS has addressed that comment under the discussion of Executive Order 12778 of this proposed rule.

9. Other Issues

FSIS received several comments on other issues, such as face-to-face labeling presentations with label reviewers, and changing the approval authority to a review function with increased enforcement activity. The scope of this rulemaking encompasses only the types of labeling submitted to FLD for approval and those authorized to be generically approved. FSIS believes that issues, such as face-to-face labeling presentations, are outside the scope of this rulemaking, and, thus, is not considering such comments at this time.

Proposed Rule

This proposed rule would require official establishments and establishments certified by responsible officials of foreign inspection systems to submit only sketch labeling in those instances where labeling is required to be submitted to FLD for approval. FSIS is proposing to limit the types of labeling submitted for review and approval for domestic and imported products and to revise 9 CFR 317.4, 317.5, 381.132, 381.133, 327.14, 381.205, and 381.206. No final labeling would be approved by FLD, except for temporary labeling approvals. This proposal would define a sketch label as a printer's proof or equivalent which clearly shows all labeling features (as set forth in 9 CFR 317.2 and 381, subpart N), size, location, and indication of final color, and is no larger than 8½×14 inches. This proposed size requirement is a result of the Agency's efforts to automate the review process and to use scanning technology to record certain information from the label application. A parent company for a corporation need only submit one labeling application for a product produced in other establishments which are owned by the corporation, since this would reduce the burdens on the industry and the Agency in submitting and revising such applications without posing any apparent risk of misbranding. Once a sketch is approved, the establishment would have the authority to print a final copy and use the labeling without my any further authorization from the Agency.

Establishments would still be required to assure that the labeling is not false or misleading in any particular. If an establishment chooses to modify an approved sketch label, the establishment would be authorized to use the final label if such labeling complies with the requirements proposed in 9 CFR 317.5, 327.14, 381.133, and 381.205. If the labeling is not in accord with these proposed provisions, the labeling would be required to be submitted as a sketch for approval by FLD.

Final labeling would be used with no further authorization from FSIS. Since the labeling would have been previously approved by FSIS in the sketch form, the Agency believes that there would be little, if any, risk of misbranding.

The Agency is proposing to revise the IIC and generic approval authorities prescribed in §§ 317.4(e), 317.5, 381.132(c), and 381.134 of the Federal meat and poultry products inspection regulations (9 CFR 317.4(e), 317.5, 381.132(c), and 381.134). This action would alleviate the burden of labeling approval from the IIC inspection activities. The IIC would retain the authority to approve meat carcass ink brands and meat food product ink and burning brands. All other provisions of 9 CFR 317.4(e) and 317.5 and of 9 CFR 381.132(c) and 381.134 would be combined to permit establishments to use final labeling for products in certain circumstances without the submission of a sketch to FLD and to use labeling for products for which a sketch had been approved. FSIS would add to this authority a few other provisions including the permitted use of labeling for standardized products prescribed in part 319 and subpart P, part 381, of the Federal meat and poultry inspection regulations (9 CFR part 319 and subpart P, part 381), provided such labeling does not contain special claims, such as

quality claims, nutrient content or health claims, geographical origin claims, negative claims, and guarantees, and does not represent a domestic product containing a foreign language. FSIS believes that prior submission for standardized product labeling is unnecessary because such labeling would pose little, if any, risk of misbranding since the regulatory standards specify the product name to be used on the labeling and the permitted ingredients.

Official establishments and foreign establishments certified by officials of foreign inspection systems would be permitted to use the following generically approved labeling without the submission of sketches for approval by FSIS:

1. Labeling for a product which has a standard of identity or composition as specified in part 319 or subpart P, part 381, and which does not contain any special claims, such as quality claims, nutrient content claims, health claims, negative claims, geographical origin claims, or guarantees, or which is not a domestic product labeled with a foreign language;

2. Labeling for single-ingredient products (such as beef steak or lamb chops or chicken legs or turkey breasts) which does not contain special claims, such as quality claims, nutrient content claims, health claims, negative claims, geographical origin claims, or guarantees, or which is not a domestic product labeled with a foreign language;

3. Labeling for products marked "For Export Only" in U.S. establishments which does not contain any special claims, such as quality claims, nutrient content claims, health claims, negative claims, geographical origin claims, or guarantees;

4. Labeling for containers of meat and meat food products and poultry products sold under contract specifications to Federal Government agencies, when such product is not offered for sale to the general public, provided the contract specifications include specific requirements with respect to labeling, and are made available to the IIC;

5. Labeling for shipping containers which contain fully labeled immediate containers, provided such labeling complies with § 316.13 or § 381.127.

6. Labeling for products not intended for human food, provided they comply with part 325 or § 381.152(c) and 381.193, and labeling for poultry heads and feet for export for processing as human food if they comply with § 381.190(b);

7. Inspection legends, which comply with parts 312 and 316 and with subpart M of part 381; and

8. Inserts, tags, liners, pasters, and like devices containing printed or graphic matter and for use on, or to be placed within containers, and coverings of products, provided such devices contain no reference to product and bear no misleading feature.

Official establishments and foreign establishments certified by officials of foreign inspection systems would also be permitted to use final labeling, without further authorization from FSIS, which was approved by FSIS, FLD, in sketch form if the final labeling was prepared without modification or with the following modifications:

1. All features of the labeling are proportionately enlarged or reduced, provided that all minimum size requirements specified in applicable regulations are met and the labeling is legible;

2. A substitution of the abbreviation "lb." for "pound," or "oz." for "ounce," or of the word "pound" for "lb." or "ounce" for "oz.";

3. A master or stock label has been approved from which the name and address of the distributor are omitted and such name and address are applied before being used (in such case, the words "prepared for" or similar statement must be shown together with the blank space reserved for the insertion of the name and address when such labels are offered for approval);

4. During holiday seasons, wrappers or other covers bearing floral or foliage designs or illustrations of rabbits, chicks, fireworks, or other emblematic holiday designs are used with approved labeling (the use of such designs will not make necessary the application of labeling not otherwise required);

5. A change in the language or the arrangement of directions pertaining to the opening of containers or the serving of the product;

6. The addition, deletion, or amendment of a dated or undated coupon, a cents-off statement, cooking instructions, packer product code information, or UPC product code information;

7. Any change in the name or address of the packer, manufacturer or distributor that appears in the signature line;

8. Any change in the net weight, provided the size of the net weight statement complies with § 317.2 or § 381.121;

9. The addition, deletion, or amendment of recipe suggestions for the product;

10. Any change in punctuation;

11. Newly assigned or revised establishment numbers for a particular establishment for which use of the labeling has been approved by the FLD;

12. The addition or deletion of open dating information;

13. A change in the type of packaging material on which the label is printed;

14. Brand name changes, provided that there are no design changes, the brand name does not use a term that connotes quality or other product characteristics, the brand name has no geographic significance, and the brand name does not affect the name of the product;

15. The deletion of the word "new" on new product labeling;

16. The addition, deletion, or amendment of special handling statements, such as "Keep Refrigerated" or "Keep Frozen," provided that the change is consistent with § 317.2 or § 381.125;

17. The addition of safe handling instructions as required by § 317.2(l) or § 381.125(b).

18. Changes reflecting a change in the quantity of an ingredient shown in the formula without a change in the order of predominance shown on the label, provided the change in quantity of ingredients complies with any minimum or maximum limits for the use of such ingredients prescribed in parts 318 and 319, or § 381.147 or subpart P of part 381;

19. Changes in the color of the labeling, provided that sufficient contrast and legibility remain;

20. The addition, deletion, or substitution of the official USDA grade shield on labels of poultry products;

21. A change in the product vignette, provided the change does not affect mandatory labeling information or misrepresent the content of the package; or

22. A change in an establishment number by a corporation or parent company for an establishment under its ownership.

Section 327.15 of the Federal meat inspection regulations (9 CFR 327.15) requires that all labeling used with outside containers of foreign meat product must be approved in accordance with part 317 of the Federal meat inspection regulations. However, 9 CFR 381.206 dealing with shipping containers of imported poultry products does not include such a provision. This proposal would amend 9 CFR 381.206 by adding a provision to require that shipping containers of imported poultry products be approved in accordance with subpart N of part 381 of the poultry products inspection regulations. This would provide consistency between

imported meat products and imported poultry products, and would clarify that labeling approval for imported products would be the same as for domestic products.

This proposal would transfer the responsibility of maintaining updated generically approved labeling records from the IIC to the official establishment in the United States and would require establishments certified by officials of a foreign inspection system to maintain such records. It would also require establishments to maintain records of labeling approved by FLD. In order to monitor compliance of regulatory labeling requirements, FSIS is proposing that establishments maintain records on all labeling used, and to make such records available to any authorized USDA official upon request. Each record would consist of a copy of the labeling and product formulation and processing procedure. Official establishments would no longer present to the IIC a copy of the generically approved labeling prior to its use, as is currently required under 9 CFR 317.5 and 381.134.

Sections 306.5, 327.24, 381.35 and 381.202(d) of the meat and poultry regulations (9 CFR 306.5, 327.24, 381.35, and 381.202(d)) specify the appeal procedures to be followed for decisions made by program employees or importers. These sections also state that denial of a labeling application by the IIC or inspector is not a basis for appeal under these sections. Since the proposed rule would not maintain the IIC's authority to approve labeling applications, there would no longer be a need to retain this provision. Therefore, these provisions would be removed from these sections.

FSIS is proposing to randomly select samples of generically approved labeling from official establishments and establishments certified under a foreign inspection system for checking compliance with labeling requirements. If the Agency would find that any such labeling is false or misleading in any particular, FSIS would initiate the proceedings set forth in 9 CFR 335.12 and 381.233 for domestic and imported products. These provisions provide generally that the Administrator notify, in writing, the person, firm, or corporation using the labeling or proposing to use the labeling that such labeling has been determined to be false or misleading and that use of such labeling shall be withheld unless the labeling is corrected. The person, firm, or corporation is provided an opportunity to respond to the Administrator's notification and a right to request a hearing regarding the merits or validity of the withholding action. Effective upon service of the notification, the use of the labeling shall be withheld, if the Administrator directs it to be withheld from use. Any hearing proceedings are governed by the Uniform Rules of Practice at (7 CFR 1.130 *et seq.*).

Although this proposed rule would not change the authority of temporary labeling approvals currently specified in 9 CFR 317.4(d) and 381.132(b), the provisions for temporary approvals are proposed at 9 CFR 317.4(g) and 381.132(g). Final labeling deficient in some particular may be granted a temporary approval up to 180 days, provided, among other things, the product is not misrepresented, as set forth in these proposed regulations, and such an approval may be extended under certain circumstances. Temporary labeling approval requests would continue to be handled the same as sketch labeling approvals through submittal of labeling applications to FLD.

This proposal would also remove the provision set forth in § 317.4(b) requiring that paper takeoffs of lithographed labels, in lieu of sections of the metal containers, be submitted to the Agency for approval. The provision was intended to assist producers of canned products when submitting a final label. Because FLD would no longer review final labels, such provision would not be necessary.

This proposal would also provide generic approval for domestic products marked "For Export Only." These products represent a limited category of products whose labeling generally will have been previously reviewed and approved by FSIS.

The Agency is proposing this action to reduce the regulatory burden placed on industry without compromising the truthfulness and accuracy of meat and poultry product labeling, and to improve production efficiency and quality of labeling review and approval.

This proposal would eliminate duplicative and unnecessary submissions. The proposed submittal of only sketch labeling would result in a more efficient approval process, as well as providing a savings to the regulated industry. FSIS, under this proposal, would sample generically approved labeling to assure the public is provided with labeling that is accurate and not misleading. This proposed rule is the first step in streamlining the labeling approval system. An all generic system may be proposed in the future if such generic approval system is found to assure accurate and truthful labeling.

List of Subjects

9 CFR Part 306

Appeals, Meat inspection.

9 CFR Part 317

Labeling, Meat inspection.

9 CFR Part 320

Records, Registration, Reports.

9 CFR Part 327

Imports, Food labeling, Meat inspection.

9 CFR Part 381

Appeals, Imports, Labeling, Poultry inspection, Records, Registration, Reports.

For the reasons set forth in the preamble, FSIS is proposing to amend 9 CFR parts 306, 317, 320, 327, and 381 of the Federal meat and poultry inspection regulations as follows:

PART 306—ASSIGNMENT AND AUTHORITIES OF PROGRAM EMPLOYEES

1. The authority citation for part 306 would continue to read as follows:

Authority: 21 U.S.C. 601–695; 7 CFR 2.17, 2.55.

2. Section 306.5 would be amended by removing the last sentence.

PART 317—LABELING, MARKING DEVICES, AND CONTAINERS

3. The authority citation for part 317 would continue to read as follows:

Authority: 21 U.S.C. 601–695; 7 CFR 2.17, 2.55.

4. Section 317.4 would be revised to read as follows:

§ 317.4 Labeling approval.

(a) No final labeling shall be used on any product unless the sketch labeling of such final labeling has been submitted for approval to the Food Labeling Division, Regulatory Programs, Food Safety and Inspection Service, and approved by such division, accompanied by FSIS Form 7234, Application for Approval of Labels, Marking, and Devices, except for generically approved labeling authorized for use in § 317.5. The management of the official establishment or establishment certified under a foreign inspection system, in accordance with part 327 of this subchapter, must maintain a copy of all labeling used, along with the product formulation and processing procedure, in accordance with part 320 of this subchapter. Such records shall be made available to any duly authorized

representative of the Secretary upon request.

(b) The Food Labeling Division shall permit submission for approval of only sketch labeling, as defined in § 317.4(d), for all products, except as provided in § 317.5 and except for temporary use of final labeling as prescribed in paragraph (g) of this section.

(c) All labeling required to be submitted for approval as set forth in 317.4(a) shall be submitted in triplicate to the Food Labeling Division, Regulatory Programs, Food Safety and Inspection Service, U.S. Department of Agriculture, Washington, DC 20250.

(d) "Sketch" labeling is a printer's proof or equivalent which clearly shows all labeling features, size, location, and indication of final color, as specified in § 317.2, and is no larger than 8½ x 14 inches.

(e) Inserts, tags, liners, pasters, and like devices containing printed or graphic matter and for use on, or to be placed within, containers and coverings of product shall be submitted for approval in the same manner as provided for labeling in § 317.4(a), except that such devices which contain no reference to product and bear no misleading feature shall be used without submission for approval as prescribed in § 317.5(b)(8).

(f)(1) Consistent with the requirements of this section, temporary approval for the use of a final label or other final labeling that may otherwise be deemed deficient in some particular may be granted by the Food Labeling Division. Temporary approvals may be granted for a period not to exceed 180 calendar days, under the following conditions:

(i) The proposed labeling would not misrepresent the product;

(ii) The use of the labeling would not present any potential health, safety, or dietary problems to the consumer;

(iii) Denial of the request would create undue economic hardship; and

(iv) An unfair competitive advantage would not result from the granting of the temporary approval.

(2) Extensions of temporary approvals may also be granted by the Food Labeling Division provided that the applicant demonstrates that new circumstances, meeting the above criteria, have developed since the original temporary approval was granted.

(g) The inspector-in-charge shall approve meat carcass ink brands and meat food product ink and burning brands, which comply with parts 312 and 316 of this subchapter.

5. Section 317.5 would be revised to read as follows:

§ 317.5 Generically approved labeling.

(a)(1) An official establishment or an establishment certified under a foreign inspection system, in accordance with Part 327 of this subchapter, is authorized to use generically approved labeling, as defined in paragraph (b) of this section, without such labeling being submitted for approval to the Food Safety and Inspection Service in Washington or the field, provided the labeling is in accordance with this section and shows all mandatory features in a prominent manner as required in § 317.2, and is not otherwise false or misleading in any particular.

(2) The Food Safety and Inspection Service shall randomly select samples of generically approved labeling from the records maintained by official establishments and establishments certified under foreign inspection systems, in accordance with Part 327 of this subchapter, as required in § 317.4, to determine compliance with labeling requirements. Any finding of false or misleading labeling shall institute the proceedings prescribed in § 335.12.

(b) Generically approved labeling is labeling which complies with the following:

(1) Labeling for a product which has a standard of identity or composition as specified in part 319 and which does not contain any special claims, such as quality claims, nutrient content claims, health claims, negative claims, geographical origin claims, or guarantees, or which is not a domestic product labeled with a foreign language;

(2) Labeling for single-ingredient products (such as beef steak or lamb chops) which does not contain any special claims, such as quality claims, nutrient content claims, health claims, negative claims, geographical origin claims, or guarantees, or which is not a domestic product labeled with a foreign language;

(3) Labeling for products marked "For Export Only" in United States establishments which does not contain any special claims, such as quality claims, nutrient content claims, health claims, negative claims, geographical origin claims, or guarantees;

(4) Labeling for containers of products sold under contract specifications to Federal Government agencies, when such product is not offered for sale to the general public, provided that the contract specifications include specific requirements with respect to labeling, and are made available to the inspector-in-charge;

(5) Labeling for shipping containers which contain fully labeled immediate containers, provided such labeling complies with § 316.13;

(6) Labeling for products not intended for human food, provided they comply with part 325;

(7) Meat inspection legends, which comply with parts 312 and 316;

(8) Inserts, tags, liners, pasters, and like devices containing printed or graphic matter and for use on, or to be placed within containers, and coverings of products, provided such devices contain no reference to product and bear no misleading feature; and

(9) Labeling which was previously approved by the Food Labeling Division as sketch labeling, and the final labeling was prepared without modification or with the following modifications:

(i) All features of the labeling are proportionately enlarged or reduced, provided that all minimum size requirements specified in applicable regulations are met and the labeling is legible;

(ii) There is a substitution of the abbreviation "lb." for "pound," or "oz." for "ounce," or of the word "pound" for "lb." or "ounce" for "oz.";

(iii) A master or stock label has been approved from which the name and address of the distributor are omitted and such name and address are applied before being used (in such case, the words "prepared for" or similar statement must be shown together with the blank space reserved for the insertion of the name and address when such labels are offered for approval);

(iv) During holiday seasons, wrappers or other covers bearing floral or foliage designs or illustrations of rabbits, chicks, fireworks, or other emblematic holiday designs are used with approved labeling (the use of such designs will not make necessary the application of labeling not otherwise required);

(v) A change in the language or the arrangement of directions pertaining to the opening of containers or the serving of the product;

(vi) The addition, deletion, or amendment of a dated or undated coupon, a cents-off statement, cooking instructions, packer product code information, or UPC product code information;

(vii) Any change in the name or address of the packer, manufacturer or distributor that appears in the signature line;

(viii) Any change in the net weight, provided the size of the net weight statement complies with § 317.2;

(ix) The addition, deletion, or amendment of recipe suggestions for the product;

(x) Any change in punctuation;

(xi) Newly assigned or revised establishment numbers for a particular establishment for which use of the

labeling has been approved by the Food Labeling Division, Regulatory Programs;

(xii) The addition or deletion of open dating information;

(xiii) A change in the type of packaging material on which the label is printed;

(xiv) Brand name changes, provided that there are no design changes, the brand name does not use a term that connotes quality or other product characteristics, the brand name has no geographic significance, and the brand name does not affect the name of the product;

(xv) The deletion of the word "new" on new product labeling;

(xvi) The addition, deletion, or amendment of special handling statements, provided that the change is consistent with § 317.2(k);

(xvii) The addition of safe handling instructions as required by § 317.2(l);

(xviii) Changes reflecting a change in the quantity of an ingredient shown in the formula without a change in the order of predominance shown on the label, provided that the change in quantity of ingredients complies with any minimum or maximum limits for the use of such ingredients prescribed in parts 318 and 319 of this subchapter;

(xix) changes in the color of the labeling, provided that sufficient contrast and legibility remain;

(xx) A change in the product vignette, provided that the change does not affect mandatory labeling information or misrepresent the content of the package; and

(xxi) A change in the establishment number by a corporation or parent company for an establishment under its ownership.

PART 320—RECORDS, REGISTRATION, AND REPORTS

6. The authority citation for part 320 would continue to read as follows:

Authority: 21 U.S.C. 601–695; 7 CFR 2.17, 2.55.

7. Section 320.1 would be amended by adding a new paragraph (b)(9) to read as follows:

§ 320.1 Records required to be kept.

* * * * *

(b) * * *

(9) Records of all labeling, along with the product formulation and processing procedures, as prescribed in § 317.4 and § 317.5.

PART 327—IMPORTED PRODUCTS

8. The authority citation for part 327 would continue to read as follows:

Authority: 21 U.S.C. 601–695; 7 CFR 2.17, 2.55.

9. Section 327.14(c) would be revised to read as follows:

§ 327.14 Marking of products and labeling of immediate containers thereof for importation.

* * * * *

(c) All marks and other labeling for use on or with immediate containers, as well as private brands on carcasses or parts of carcasses, shall be approved by the Food Safety and Inspection Service in accordance with part 317 of this subchapter before products bearing such marks, labeling, or brands will be entered into the United States. The marks of inspection of foreign systems embossed on metal containers or branded on carcasses or parts thereof need not be submitted to the Food Safety and Inspection Service for approval, and such marks of inspection put on stencils, box dies, labels, and brands may be used on such immediate containers as tierces, barrels, drums, boxes, crates, and large-size fiberboard containers of foreign products without such marks of inspection being submitted for approval, provided the markings made by such articles are applicable to the product and are not false or misleading.

10. Section 327.24 would be amended by removing the last sentence.

PART 381—POULTRY PRODUCTS INSPECTION REGULATIONS

11. The authority citation for part 381 would continue to read as follows:

Authority: 7 U.S.C. 450, 21 U.S.C. 451–470; 7 CFR 2.17, 2.55.

12. Section 381.35 would be amended by revising the last sentence to read as follows:

§ 381.35 Appeal inspections; how made.

* * *. The poultry or poultry products involved in any appeal shall be identified by U.S. retained tags and segregated in a manner approved by the inspector pending completion of an appeal inspection.

13. Section 381.1342 would be revised to read as follows:

§ 381.132 Labeling approval.

(a) No final labeling shall be used on any product unless the sketch labeling of such final labeling has been submitted for approval to the Food Labeling Division, Regulatory Programs, Food Safety and Inspection Service, and approved by such division, accompanied by FSIS Form 7234, Application for Approval of Labels, Marking, and Devices, except for generically approved labels authorized for use in § 381.133. The management of the official establishment or establishment certified under a foreign inspection system, in accordance with subpart T of this part, must maintain a copy of all labeling used, along with the product formulation and processing procedure, in accordance with subpart Q of this part. Such records shall be made available to any duly authorized representative of the Secretary upon request.

(b) The Food Labeling Division shall permit submission for approval of only sketch labeling, as defined in § 381.132(d), for all products, except as provided in § 381.133 and except for temporary use of final labeling as prescribed in paragraph (g) of this section.

(c) All labeling required to be submitted for approval as set forth in § 381.132(b) shall be submitted in triplicate to the Food Labeling Division, Regulatory Programs, Food Safety and Inspection Service, U.S. Department of Agriculture, Washington, DC 20250.

(d) "Sketch" labeling is a printer's proof or equivalent which clearly shows all labeling features, size, location, and indication of final color, as specified in subpart N of this part, and is no larger than 8½ x 14 inches.

(e) Inserts, tags, liners, pasters, and like devices containing printed or graphic matter and for use on, or to be placed within, containers and coverings of product shall be submitted for approval in the same manner as provided for labeling in § 381.132(a), except that such devices which contain no reference to product and bear no misleading feature shall be used without submission for approval as prescribed in § 381.133(b)(8).

(f)(1) Consistent with the requirements of this section, temporary approval for the use of a final label or other final labeling that may otherwise be deemed deficient in some particular may be granted by the Food Labeling Division. Temporary approvals may be granted for a period not to exceed 180 calendar days under the following conditions:

(i) The proposed labeling would not misrepresent the product;

(ii) The use of the labeling would not present any potential health, safety, or dietary problems to the consumer;

(iii) Denial of the request would create undue economic hardship; and

(iv) An unfair competitive advantage would not result from the granting of the temporary approval.

(2) Extensions of temporary approvals may also be granted by the Food Labeling Division, provided that the applicant demonstrates that new circumstances, meeting the above

criteria, have developed since the original temporary approval was granted.

14. Section 381.133 would be redesignated as § 381.134, and § 381.134 would be redesignated as § 381.133 and revised to read as follows:

§ 381.133 Generically approved labeling.

(a)(1) An official establishment or an establishment certified under a foreign inspection system, in accordance with subpart T of this part, is authorized to use generically approved labeling, as defined in paragraph (b) of this section, without such labeling being submitted for approval to the Food Safety and Inspection Service in Washington or the field, provided the labeling is in accord with this section and shows all mandatory features in a prominent manner as required in Subpart N of this part, and is not otherwise false or misleading in any particular.

(2) The Food Safety and Inspection Service shall randomly select samples of generically approved labeling from the records maintained by official establishments and establishments certified under foreign inspection systems, in accordance with subpart T of this part, as required in § 381.132, to determine compliance with labeling requirements. Any finding of false or misleading labeling shall institute the proceedings prescribed in § 381.233.

(b) Generically approved labeling is labeling which complies with the following:

(1) Labeling for a product which has a standard of identity or composition as specified in subpart P of this part and which does not contain any special claims, such as quality claims, nutrient content claims, health claims, negative claims, geographical origin claims, or guarantees, or which is not a domestic product labeled with a foreign language;

(2) Labeling for single-ingredient products (such as chicken legs or turkey breasts) which does not contain any special claims, such as quality claims, nutrient content claims, health claims, negative claims, geographical origin claims, or guarantees, or which is not a domestic product labeled with a foreign language;

(3) Labeling for products marked "For Export Only" in United States establishments which does not contain any special claims, such as quality claims, nutrient content claims, health claims, negative claims, geographical origin claims, or guarantees;

(4) Labeling for containers of products sold under contract specifications to Federal Government agencies, when such product is not offered for sale to the general public, provided that the contract specifications include specific requirements with respect to labeling, and are made available to the inspector-in-charge;

(5) Labeling for shipping containers which contain fully labeled immediate containers, provided such labeling complies with § 381.127;

(6) Labeling for products not intended for human food, provided they comply with § 381.152(c) and § 381.193, and labeling for poultry heads and feet for export for processing as human food if they comply with § 381.190(b);

(7) Poultry inspection legends, which comply with subpart M of this part;

(8) Inserts, tags, liners, pasters, and like devices containing printed or graphic matter and for use on, or to be placed within containers, and coverings of products, provided such devices contain no reference to product and bear no misleading feature; and

(9) Labeling which was previously approved by the Food Labeling Division as sketch labeling, and the final labeling was prepared without modification or with the following modifications:

(i) All features of the labeling are proportionately enlarged or reduced, provided that all minimum size requirements specified in applicable regulations are met and the labeling is legible;

(ii) There is a substitution of the abbreviation "lb." for "pound," or "oz." for "ounce," or of the word "pound" for "lb." or "ounce" for "oz.";

(iii) A master or stock label has been approved from which the name and address of the distributor are omitted and such name and address are applied before being used (in such case, the words "prepared for" or similar statement must be shown together with the blank space reserved for the insertion of the name and address when such labels are offered for approval);

(iv) During holiday seasons, wrappers or other covers bearing floral or foliage designs or illustrations of rabbits, chicks, fireworks, or other emblematic holiday designs are used with approved labeling (the use of such designs will not make necessary the application of labeling not otherwise required);

(v) A change in the language or the arrangement of directions pertaining to the opening of containers or the serving of the product;

(vi) The addition, deletion, or amendment of a dated or undated coupon, a cents-off statement, cooking instructions, packer product code information, or UPC product code information;

(vii) Any change in the name or address of the packer, manufacturer or distributor that appears in the signature line;

(viii) Any change in the net weight, provided that the size of the net weight statement complies with § 381.121;

(ix) The addition, deletion, or amendment of recipe suggestions for the product;

(x) Any change in punctuation;

(xi) Newly assigned or revised establishment numbers for a particular establishment for which use of the labeling has been approved by the Food Labeling Division, Regulatory Programs;

(xii) The addition or deletion of open dating information;

(xiii) A change in the type of packaging material on which the label is printed;

(xiv) Brand name changes, provided that there are no design changes, the brand name does not use a term that connotes quality or other product characteristics, the brand name has no geographic significance, and the brand name does not affect the name of the product;

(xv) The deletion of the word "new" on new product labeling;

(xvi) The addition, deletion, or amendment of special handling statements, provided that the change is consistent with § 381.125(a);

(xvii) The addition of safe handling instructions as required by § 381.125(b);

(xviii) Changes reflecting a change in the quantity of an ingredient shown in the formula without a change in the order of predominance shown on the label, provided that the change in quantity of ingredients complies with any minimum or maximum limits for the use of such ingredients prescribed in § 381.147 and subpart P of this part;

(xix) Changes in the color of the labeling, provided that sufficient contrast and legibility remain;

(xx) A change in the product vignette, provided that the change does not affect mandatory labeling information or misrepresent the content of the package;

(xxi) The addition, deletion, or substitution of the official USDA poultry grade shield; and

(xxii) A change in the establishment number by a corporation or parent company for an establishment under its ownership.

15. Section 381.175 would be amended by adding a new paragraph (b)(6) to read as follows:

§ 381.175 Records required to be kept.

* * * * *

(b) * * *

(6) Records of all labeling, along with the product formulation and processing procedures, as prescribed in § 381.132 and § 381.133.

16. Section 381.202(d) would be amended by removing the last sentence and by revising the next to the last sentence to read as follows:

§ 381.202 Poultry products offered for entry; reporting of findings to customs; handling of articles refused entry; appeals, how made; denaturing procedures.

* * * * *

(d) * * *. The poultry or poultry products involved in any appeal shall be identified by U.S. retained tags and segregated in a manner approved by the inspector pending completion of an appeal inspection.

* * * * *

16. Section 381.205(c) would be revised to read as follows:

§ 381.205 Labeling of immediate containers of poultry products offered for entry.

* * * * *

(c) All marks and other labeling for use on or with immediate containers shall be approved for use by the Food Safety and Inspection Service in accordance with § 381.132 and § 381.133 before products bearing such marks and other labeling will be permitted for entry into the United States.

17. Section 381.206 would be amended by adding to the end thereof the following sentence:

§ 381.206 Labeling of shipping containers of poultry products offered for entry.

* * *. All labeling used with a shipping container of imported poultry products must be approved in accordance with subpart N of this part.

Done at Washington, DC, on November 16, 1993.

Eugene Branstool,

Assistant Secretary for Marketing and Inspection Services.

[FR Doc. 93–28624 Filed 11–22–93, 8:45 am]

BILLING CODE 3410–DM–M

federal register

Tuesday
November 23, 1993

Part VI

Securities and Exchange Commission

17 CFR Part 229, et al.
Amendments to the Multijurisdictional Disclosure System for Canadian Issuers; Final Rule

SECURITIES AND EXCHANGE COMMISSION

17 CFR Parts 229, 230, 239 and 249

[Release Nos. 33–7025; 34–33134; International Series Release No. 604; File No. S7–16–93]

RIN 3235–AF83

Amendments to the Multijurisdictional Disclosure System for Canadian Issuers

AGENCY: Securities and Exchange Commission.

ACTION: Final amendments to rules and forms.

SUMMARY: The Securities and Exchange Commission (the "Commission") is adopting amendments to rules and forms relating to the multijurisdictional disclosure system ("MJDS") with Canada, including revisions which would modify the eligibility requirements for use of Forms F–9 and F–10 and recognize investment grade ratings by securities rating organizations recognized by Canadian securities regulators for purposes of filings on Forms F–9 and 40–F. These amendments are being adopted in light of the Commission's experience with the MJDS and should further facilitate transnational capital formation.

EFFECTIVE DATE: December 23, 1993.

APPLICABILITY DATE: Filings made prior to the 30th day after publication of this release in the **Federal Register** may proceed as if the amendments adopted hereby were effective on such publication, except for the amendments to the Instruction to § 239.39(a)(2) and the Instruction to General Instruction I.A. to Form F–9, which will be effective on the date of publication of such amendments in the **Federal Register** after the Canadian securities regulators have adopted certain amendments to the MJDS for U.S. issuers described herein.

FOR FURTHER INFORMATION CONTACT: Paul M. Dudek, (202) 272–3246, Office of International Corporate Finance, Division of Corporation Finance, Securities and Exchange Commission, Washington, DC. 20549.

SUPPLEMENTARY INFORMATION:

I. Amendments to the MJDS

The multijurisdictional disclosure system for Canadian issuers, adopted on June 21, 1991, permits Canadian issuers meeting specified eligibility criteria to satisfy certain securities registration and reporting requirements of the Commission by providing disclosure documents prepared in accordance with the requirements of Canadian securities regulators.[1] Concurrently with the Commission's action, the Canadian Securities Administrators (the "CSA") adopted a parallel multijurisdictional disclosure system for U.S. issuers in Canada.[2] On April 28, 1993, the Commission proposed for comment the amendments to the MJDS discussed herein. [3] The Commission received six comment letters on these proposed amendments. These amendments are being adopted today substantially as proposed.[4]

The Commission proposed to amend the eligibility requirements under Forms F–9, F–10 and 40–F[5] to eliminate the market capitalization threshold, to establish the public float threshold at U.S. $75 million and to shorten the reporting history requirements to as short as twelve months. Commenters expressing a view on these proposals were supportive of the elimination of the market capitalization threshold and the reduction of the reporting history requirement but were opposed to changing the public float threshold from Cn $75 million to U.S. $75 million. A U.S. $75 million threshold has been established for U.S. issuers desiring to use the Commission's short form registration form and shelf registration system for primary offerings.[6] The Commission believes it is appropriate for this same dollar threshold to apply to the MJDS inasmuch as Canadian issuers using the MJDS for offerings in the United States may make use of Canadian short form registration and shelf registration procedures. The Commission is eliminating the market capitalization requirement and establishing the public float requirement as proposed. The CSA has proposed and has indicated that it will adopt amendments to shorten the reporting history requirement for use of the POP System from 36 to 12 months.[7] In light of the CSA's actions and the support expressed by commenters on the Commission's proposal, the Commission is adopting amendments to Forms F–9, F–10 and 40–F to shorten the reporting history requirement to 12 months.

The Commission also proposed to amend Form F–9 to recognize investment grade ratings by securities rating organizations recognized by Canadian securities regulators. Commenters expressing a view on this proposal were uniformly supportive. The CSA has proposed and has indicated that it will adopt parallel amendments to National Policy Statement No. 45 to recognize investment grade ratings by securities rating organizations which are deemed to be nationally recognized statistical rating organizations ("NRSROs") under the Commission's rules.[8] In light of the above, the Commission is adopting the amendments as proposed; these amendments will, however, become effective after the Canadian securities regulators adopt parallel amendments to the Canadian MJDS, as described under "Effective Date" below.

The Commission is also adopting the proposed amendments to Item 10 of Regulation S-K[9] and Rules 134 and 436 under the Securities Act of 1933[10] to include appropriate cross-references to the ratings now recognized under Form F–9. The proposed amendments to Form F–9 to provide that the required rating must be obtained at the time of sale to the public, rather than at the time of effectiveness, and to add an instruction regarding the registrant's reasonable belief of obtaining the required rating are also being adopted, as well as an

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[1] Securities Act Release No. 6902 (June 21, 1991) [56 FR 30036].

[2] National Policy Statement No. 45 of the CSA, "Multijurisdictional Disclosure System" (referred to herein as "National Policy Statement No. 45").

[3] Securities Act Release No 6997 (April 28, 1993) 58 FR 26442.

[4] The Commission also proposed amending Forms F–10 and 40–F to retain the financial statement reconciliation requirement under such forms. These amendments were adopted in June 1993. Securities Act Release No. 7004 (June 28, 1993) [58 FR 35367].

[5] 17 CFR 239.39, 239.40 and 249.40f.

[6] See Securities Act Release 6964 (Oct. 22, 1992) [57 FR 48970].

[7] The Prompt Offering Qualification system, which is known as the "POP System", has been established by Canadian securities regulators to allow substantial issuers quick access to the public securities markets. See National Policy Statement 47 of the CSA, "Prompt Offering Qualification System". Amendments to shorten the reporting history requirement under the POP System from 36 to 12 months were proposed in June 1993. See "Draft Amendments to National Policy Statement No. 47 and National Policy Statement No. 45" 16 OSC Bulletin 2889 (June 11, 1993).

[8] Market participants currently look to a no-action process administered by the staff of the Division of Market Regulation to determine which rating organizations will be treated as NRSROs for net capital purposes under Rule 15c3–1(c)(2)(vi)(F). Six rating organizations are currently treated as NRSROs for net capital purposes as a result of this process. Four of these NRSROs are not currently recognized under National Policy Statement No. 45. Under amendments to National Policy Statement No. 45, the ratings of these four rating organizations will be usable for purposes of determining whether a U.S. issuer is eligible to use the MJDS in Canada. Likewise, National Policy Statement No. 45 currently recognizes four rating organizations, two of which are not among the six rating organizations treated by the Commission staff as NRSROs for net capital purposes. Under the amendment to Form F–9 being adopted today, the ratings of these two rating organizations will be usable for purposes of determining whether a Canadian issuer is eligible to use Form F–9 or 40–F.

[9] 17 CFR 229.10.

[10] 17 CFR 230.134 and 230.436.

amendment to Form F–7 [11] relating to specifying an agent for service.

The Commission had solicited comments relating to amending the MJDS to accommodate the unallocated shelf registration of securities. The CSA has not proposed an unallocated shelf registration system and so the Commission is not taking action relating to unallocated shelf registration under the MJDS.

II. Regulatory Flexibility Act Certification

Pursuant to Section 605(b) of the Regulatory Flexibility Act [5 U.S.C. 605], at the time the Commission issued its release proposing the amendments being adopted hereby, the Chairman of the Commission certified that such amendments will not have a significant impact on a substantial number of small entities. That certification, including the reasons therefor, was attached as an Appendix to such release and was published in the **Federal Register**.

III. Cost-Benefit Analysis

No specific data were provided in response to the Commission's request regarding the costs and benefits of the amendments being adopted today. Some commenters indicated that amendments relating to recognition of investment grade ratings by securities rating organizations recognized by Canadian securities regulators would save Canadian issuers the expense of obtaining a securities rating from those rating organizations currently specified under Form F–9. Some commenters also noted that shortening the reporting history requirement under Forms F–9 and F–10 would permit newly public companies to more quickly achieve MJDS eligibility and thus a less expensive mechanism to access the U.S. capital markets.

IV. Effective and Applicability Dates

Except for the Instruction to § 239.39(a)(2) and the Instruction to General Instruction I.A. to Form F–9 as described in the next paragraph, the amendments adopted hereby shall be effective on the date specified under "Effective Date" above. In addition, except as described in the next paragraph, filings made prior to such date may proceed as if the amendments adopted hereby were effective on the date of publication of this release in the **Federal Register**.

The CSA has proposed amendments to National Policy Statement No. 45 which would expand the eligibility requirements under the Canadian MJDS for U.S. issuers.[12] These amendments proposed by the CSA would reduce the reporting history requirement, eliminate the market capitalization requirement, change the public float requirement and recognize ratings by NRSROs for purposes of the Canadian MJDS in a manner similar to the amendments being adopted today. The amendments to Form F–9 relating to recognition of ratings by rating organizations recognized by Canadian securities regulators (the Instruction to § 239.39(a)(2) and the Instruction to General Instruction I.A. to Form F–9 [13]) shall be effective on the date of publication of such amendments by the Commission in the **Federal Register** after the CSA and the provincial securities regulators have adopted substantially as proposed such amendments relating to the eligibility requirements for U.S. issuers using the MJDS in Canada. Such amendments to Form F–9 shall be effective immediately upon publication in the **Federal Register** in accordance with the Administrative Procedure Act, which allows effectiveness in less than 30 days after publication for "a substantive rule which grants or recognizes an exemption or relieves a restriction." 5 U.S.C. 553(d)(1).

V. Statutory Bases

The amendments to the Commission's rules and forms are being proposed pursuant to Sections 6, 7, 8, 10 and 19(a) of the Securities Act of 1933, and Sections 3(b), 4A, 12, 13, 14, 15, 16 and 23 of the Securities Exchange Act of 1934.

List of Subjects in 17 CFR Parts 229, 230, 239 and 249

Reporting and recordkeeping requirements; Securities.

Text of Amendments

In accordance with the foregoing, Title 17, chapter II of the Code of Federal Regulations is amended as follows:

[11] 17 CFR 239.37.

[12] See fn 7, supra.

[13] The instruction to 17 CFR 239.39(a)(2) and the Instruction to General Instruction I.A. to Form F–9 will be amended to read as follows:

Securities shall be "investment grade" if, at the time of sale, at least one nationally recognized statistical rating organization (as that term is used in relation to Rule 15c3–1(c)(2)(vi)(F) under the Securities Exchange Act of 1934 (the "Exchange Act") (§ 240.15c3–1(c)(2)(vi)(F) of this chapter)) or at least one Approved Rating Organization (as defined in National Policy Statement No. 45 of the Canadian Securities Administrators, as the same may be amended from time to time) has rated the security in one of its generic rating categories that signifies investment grade; typically the four highest rating categories (within which there may be subcategories or gradations indicating relative standing) signify investment grade.

PART 229—STANDARD INSTRUCTIONS FOR FILING FORMS UNDER SECURITIES ACT OF 1933, SECURITIES EXCHANGE ACT OF 1934 AND ENERGY POLICY AND CONSERVATION ACT OF 1975—REGULATION S–K

1. The authority citation for part 229 continues to read in part as follows:

Authority: 15 U.S.C. 77e, 77f, 77g, 77h, 77j, 77k, 77s, 77aa(25), 77aa(26), 77ddd, 77eee, 77ggg, 77hhh, 77iii, 77jjj, 77nnn, 77sss, 78c, 78i, 78j, 78l, 78m, 78n, 78o, 78w, 78ll(d), 79e, 79n, 79t, 80a-8, 80a-29, 80a-30, 80a-37, 80b-11, unless otherwise noted.

* * * * *

2. By amending § 229.10 by adding a new sentence to the end of paragraph (c)(1)(i) to read as follows:

§ 229.10 General.

* * * * *

(c) * * *

(1) * * *

(i) * * * When the registrant has filed a registration statement on Form F–9 (§ 239.39 of this chapter), see Rule 436(g) (§ 230.436(g) of this chapter) under the Securities Act with respect to the written consent of any rating organization specified in the Instruction to paragraph (a)(2) of General Instruction I of Form F–9.

* * * * *

PART 230—GENERAL RULES AND REGULATIONS, SECURITIES ACT OF 1933

3. The authority citation for Part 230 continues to read in part as follows:

Authority: 15 U.S.C. 77b, 77f, 77g, 77h, 77j, 77s, 77sss, 78c, 78*l*, 78m, 78n, 78*o*, 78w, 78*ll*(d), 79t, 80a-8, 80a-29, 80a-30, and 80a-37, unless otherwise noted.

* * * * *

4. By amending § 230.134 by revising paragraph (a)(14)(i) to read as follows:

§ 230.134 Communications not deemed a prospectus.

* * * * *

(a) * * *

(14)(i) With respect to any class of debt securities, any class of convertible debt securities or any class of preferred stock, the security rating or ratings assigned to the class of securities by any nationally recognized statistical rating organization and the name or names of the nationally recognized statistical rating organization(s) which assigned such rating(s), and with respect to any class of debt securities, any class of convertible debt securities or any class of preferred stock registered on Form F–9 (§ 239.39 of this chapter), the security rating or ratings assigned to the class of securities by any other rating

organization specified in the Instruction to paragraph (a)(2) of General Instruction I of Form F–9 and the name or names of the rating organization or organizations which assigned such rating(s).

* * * * *

5. By amending § 230.436 by revising paragraph (g)(1) to read as follows:

§ 230.436 Consents required in special cases.

* * * * *

(g)(1) Notwithstanding the provisions of paragraphs (a) and (b) of this section, the security rating assigned to a class of debt securities, a class of convertible debt securities, or a class of preferred stock by a nationally recognized statistical rating organization, or with respect to registration statements on Form F–9 (§ 239.39 of this chapter) by any other rating organization specified in the Instruction to paragraph (a)(2) of General Instruction I of Form F–9, shall not be considered a part of the registration statement prepared or certified by a person within the meaning of sections 7 and 11 of the Act.

* * * * *

PART 239—FORMS PRESCRIBED UNDER THE SECURITIES ACT OF 1933

6. The authority citation for part 239 continues to read in part as follows:

Authority: 15 U.S.C. 77f, 77g, 77h, 77j, 77s, 77sss, 78c, 78*l*, 78m, 78n, 78*o*(d), 78w(a), 78*ll*(d), 79e, 79f, 79g, 79j, 79*l*, 79m, 79n, 79q, 79t, 80a-8, 80a-29, 80a-30 and 80a-37, unless otherwise noted.

* * * * *

7. By amending Form F–7 (§ 239.37) by adding a new paragraph J to General Instruction II to read as follows:

Note: Form F–7 does not and these amendments will not appear in the Code of Federal Regulations.

Form F–7

* * * * *

GENERAL INSTRUCTIONS

* * * * *

II. Application of General Rules and Regulations

* * * * *

J. Registrants are required to name an agent for service in the United States as required by the cover page of the registration statement even though not required to file a Form F–X.

* * * * *

8. By amending § 239.39 by revising paragraph (b)(3), by removing paragraph (b)(4), redesignating paragraph (b)(5) as paragraph (b)(4), by revising newly designated paragraph (b)(4), by revising paragraph (e), to read as follows, and in paragraph (f) introductory text and paragraph (f)(1) by removing the reference "36" and adding in its place "12" each time it appears:

§ 239.39 Form F–9, for registration under the Securities Act of 1933 of certain investment grade debt or investment grade preferred securities of certain Canadian issuers.

* * * * *

(b) * * *

(3) Has been subject to the continuous disclosure requirements of any securities commission or equivalent regulatory authority in Canada for a period of at least 12 calendar months immediately preceding the filing of this Form, and is currently in compliance with such obligations; and

(4) Has an aggregate market value of the public float of its outstanding equity shares of $75 million or more; *provided, however,* that the requirement set forth in this paragraph (b)(4) shall not apply if the securities being registered on this Form are not convertible into another security.

* * * * *

(e) If the registrant is a majority-owned subsidiary offering debt securities or preferred securities, it shall be deemed to meet the requirements of paragraphs (b)(3) and (b)(4) of this section if the parent of the registrant-subsidiary meets the requirements of paragraph (b) of this section, as applicable, and fully and unconditionally guarantees the securities being registered as to principal and interest (if debt securities) or as to liquidation preference, redemption price and dividends (if preferred securities); *provided, however,* that the securities of the subsidiary are only convertible or exchangeable, if at all, for the securities of the parent.

* * * * *

9. By amending Form F–9 (§ 239.39) by revising paragraph B.(3) of General Instruction I, by removing paragraph B.(4) of General Instruction I, by redesignating paragraph B.(5) of General Instruction I as paragraph B.(4), by revising newly redesignated paragraph B.(4) of General Instruction I, by revising paragraph E. of General Instruction I and by revising Instruction D. to the Signatures, to read as follows, and in paragraph F. of General Instruction I by removing in three places the references to "36" and adding in their place "12":

Note: Form F–9 does not and these amendments will not appear in the Code of Federal Regulations.

Form F–9

* * * * *

GENERAL INSTRUCTIONS

I. Eligibility Requirements for Use of Form F–9

* * * * *

B. * * *

(3) has been subject to the continuous disclosure requirements of any securities commission or equivalent regulatory authority in Canada for a period of at least 12 calendar months immediately preceding the filing of this Form, and is currently in compliance with such obligations; and

(4) has an aggregate market value of the public float of its outstanding equity shares of $75 million or more; *provided, however,* that the requirements set forth in this B.(4) shall not apply if the securities being registered on this Form are not convertible into another security.

* * * * *

E. If the Registrant is a majority-owned subsidiary offering debt securities or preferred securities, it shall be deemed to meet the requirements of I.B. (3) and (4) above if the parent of the Registrant-subsidiary meets the requirements of I.B. above, as applicable, and fully and unconditionally guarantees the securities being registered as to principal and interest (if debt securities) or as to liquidation preference, redemption price and dividends (if preferred securities); *provided, however,* that the securities of the subsidiary are only convertible or exchangeable, if at all, for the securities of the parent.

* * * * *

SIGNATURES

* * * * *

Instructions

* * * * *

D. Where eligibility for use of this Form is based on the assignment of a security rating, the Registrant may sign the registration statement notwithstanding the fact that such security rating has not been assigned by the filing date, provided that the Registrant reasonably believes, and so states, that the security rating requirement will be met by the time of sale.

10. By amending § 239.40 in paragraph (c)(3) by removing the reference "36" and adding in its place "12" each time it appears and adding the word "and" after the semi-colon at the end of paragraph (c)(3), by removing paragraph (c)(4), by redesignating paragraph (c)(5) as paragraph (c)(4), by revising newly designated paragraph (c)(4) as set forth below, and in paragraph (h) by removing the reference "paragraphs (c)(3), (c)(4) and (c)(5)" and adding in its place "paragraphs (c)(3) and (c)(4)" and in paragraph (i) introductory text and paragraph (i)(1) by removing the reference "36" and adding in its place "12" each time it appears:

§ 239.40 Form F–10, for registration under the Securities Act of 1933 of securities of certain Canadian issuers.

* * * * *

(c) * * *

(4) Has an aggregate market value of the public float of its outstanding equity shares of $75 million or more; *provided, however,* that in the case of a business combination, the aggregate market value of the public float of the outstanding equity shares of each participating company other than the successor registrant is $75 million or more, except that any such participating company shall not be required to meet such public float requirement if other participating companies whose assets and gross revenues, respectively, would contribute at least 80 percent of the total assets and gross revenues from continuing operations of the successor registrant, as measured based on pro forma combination of the participating companies' most recently completed fiscal years, each meet such public float requirement; and *provided, further,* that in the case of a business combination, such public float requirement shall be deemed satisfied in the case of a participating company whose equity shares were the subject of an exchange offer that was registered or would have been eligible for registration on Form F–8, Form F–9, Form F–10 or Form F–80 (§§ 239.38, 239.39, 239.40 or 239.41) or a tender offer in connection with which Schedule 13E–4F or 14D–1F (§§ 240.13e–102 or 240.14d–102 of this chapter) was filed or could have been filed, that terminated within the last twelve months, if the participating company would have satisfied such public float requirement immediately prior to commencement of such exchange or tender offer.

* * * * *

11. By amending Form F–10 (§ 239.40) in paragraph C.(3) of General Instruction I by removing in two places references to "36" and adding in their place "12" and adding the word "and" after the semi-colon at the end of paragraph C.(3) of General Instruction I, by removing paragraph C.(4) of General Instruction I, by redesignating paragraph C.(5) of General Instruction I as paragraph C.(4), by revising newly redesignated paragraph C.(4) of General Instruction I and by revising paragraph H. of General Instruction I, to read as follows, and in paragraph I. of General Instruction I by removing in three places references to "36" and adding in their place "12":

Note: Form F–10 does not and these amendments will not appear in the Code of Federal Regulations.

Form F–10

* * * * *

GENERAL INSTRUCTIONS

I. General Eligibility Requirements for Use of Form F–10

C. * * *

(4) has an aggregate market value of the public float of its outstanding equity shares of $75 million or more; *provided, however,* that in the case of a business combination, the aggregate market value of the public float of the outstanding equity shares of each participating company other than the successor Registrant is $75 million or more, except that any such participating company shall not be required to meet such public float requirement if other participating companies whose assets and gross revenues, respectively, would contribute at least 80 percent of the total assets and gross revenues from continuing operations of the successor Registrant, as measured based on pro forma combination of the participating companies' most recently completed fiscal years, each meet such public float requirement; and *provided, further,* that in the case of a business combination, such public float requirement shall be deemed satisfied in the case of a participating company whose equity shares were the subject of an exchange offer that was registered or would have been eligible for registration on Form F–8, Form F–9, Form F–10 or Form F–80, or a tender offer in connection with which Schedule 13E–4F or 14D–1F was filed or could have been filed, that terminated within the last twelve months, if the participating company would have satisfied such public float requirement immediately prior to commencement of such exchange or tender offer.

* * * * *

H. With respect to registration of debt securities or preferred securities on this Form, if the Registrant is a majority-owned subsidiary, it shall be deemed to meet the requirements of I.C.(3) and (4) above if the parent of the Registrant-subsidiary meets the requirements of I.C. above and fully and unconditionally guarantees the securities being registered as to principal and interest (if debt securities) or as to liquidation preference, redemption price and dividends (if preferred securities); *provided, however,* that the securities of the subsidiary are only convertible or exchangeable, if at all, for the securities of the parent.

PART 249—FORMS, SECURITIES EXCHANGE ACT OF 1934

12. The authority citation for Part 249 continues to read in part as follows:

Authority: 15 U.S.C. 78a, *et seq.,* unless otherwise noted.

* * * * *

13. By amending § 249.240f by revising paragraph (b)(3), by removing paragraph (b)(4), redesignating paragraph (b)(5) as paragraph (b)(4) and by revising newly designated paragraph (b)(4), to read as follows, and in paragraph (c) introductory text and paragraph (c)(1) by removing the reference "36" and adding in its place "12" each time it appears:

§ 249.240f Form 40–F, for registration of securities of certain Canadian issuers pursuant to section 12(b) or (g) and for reports pursuant to section 15(d) and Rule 15d–4 (§ 240.15d–4 of this chapter).

* * * * *

(b) * * *

(3) The registrant has been subject to the periodic reporting requirements of any securities commission or equivalent regulatory authority in Canada for a period of at least 12 calendar months immediately preceding the filing of this Form and is currently in compliance with such obligations; and

(4) The aggregate market value of the public float of the registrant's outstanding equity shares is $75 million or more; *provided, however,* no market value threshold need be satisfied in connection with non-convertible securities eligible for registration on Form F–9 (§ 239.39 of this chapter).

* * * * *

14. By amending Form 40–F (§ 249.240f) by revising clause (iii) of paragraph (2) of General Instruction A., by removing clause (iv) of paragraph (2) of General Instruction A., by redesignating clause (v) of paragraph (2) of General Instruction A. as clause (iv) and by revising newly redesignated clause (iv) of paragraph (2) of General Instruction A., to read as follows, and in paragraph (3) of General Instruction A in three places by removing the references "36" and adding in their place "12":

Note: Form 40–F does not and these amendments will not appear in the Code of Federal Regulations.

Form 40–F

* * * * *

GENERAL INSTRUCTIONS

A. *Rules As To Use of Form 40–F*

* * * * *

(2) * * *

(iii) the Registrant has been subject to the periodic reporting requirements of any securities commission or equivalent regulatory authority in Canada for a period of at least 12 calendar months immediately preceding the filing of this Form and is currently in compliance with such obligations; and

(iv) the aggregate market value of the public float of the Registrant's outstanding equity shares is $75 million or more; *provided, however,* that no market value threshold need be satisfied in connection with non-convertible securities eligible for registration on Form F–9.

* * * * *

By the Commission.

Dated: November 3, 1993.

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. 93–28684 Filed 11–22–93; 8:45 am]

BILLING CODE 8010–01–M

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